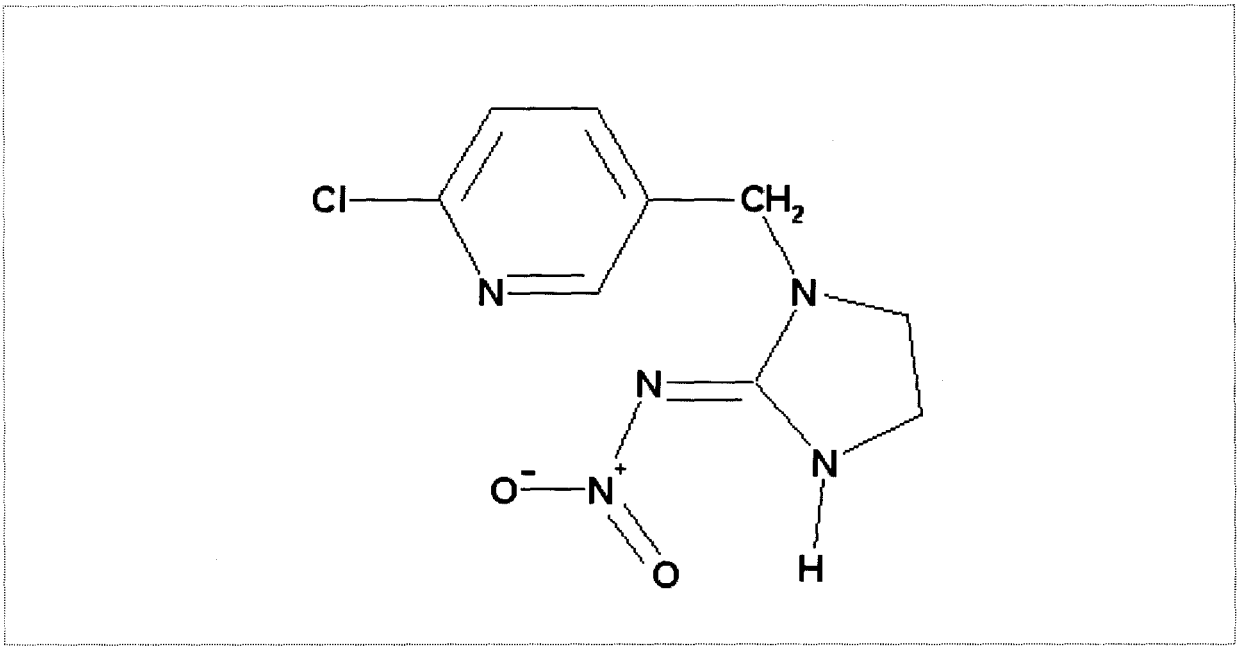
EPA
United States
Environmental Protection
Agency

IR4 Petition for the Use of Imidacloprid on Shellfish Beds in Willapa Bay and Grays Harbor, State of Washington (PC 129099); D399685, 399877, 399882



Date: 03/13/13 *Prepared by:* Joseph DeCant, Ecologist Michael Barrett, Senior Chemist	*U. S. Environmental Protection Agency* *Office of Pesticide Programs* *Environmental Fate and Effects Division* *Environmental Risk Branch IV* *1200 Pennsylvania Ave., NW* *Mail Code 7507P* *Washington, DC 20460*
Approved by: Mah Shamim, PhD, Branch Chief	

Contents

Executive Summary

IR4 requests registrations for the uses of Protector 2F and 0.5G (imidacloprid as the active ingredient) for the control of ghost and mud shrimp on shellfish beds in Willapa Bay and Grays Harbor, Washington. The proposed labels for Protector 2F (flowable concentrate) and 0.5G (granular) allow for one application of imidacloprid at 0.5 lb a.i./acre per year.

The primary organisms of concern due to direct toxicity from both acute and chronic exposure are the benthic and free-swimming estuarine/marine invertebrates. The use of the flowable and granular formulations presents a risk that exceeds all LOC's at onsite locations on an acute basis for free-swimming invertebrates and benthic invertebrates that inhabit the sediment. In terms of chronic exposure, the RQ's exceed the LOC's at onsite locations for both flowable and granular formulations for benthic invertebrates. Free-swimming invertebrates are also at risk due to chronic exposure on the site of application. In contrast to modeling results, the submitted monitoring report indicates that the overlying water contains very little parent imidacloprid at 21 days post application and would likely not impact free-swimming invertebrates in the overlying water following chronic exposure. These data have not been formally submitted, represent only a partial submission of collected data, and have not been reviewed by EFED. Consequently there is uncertainty in any conclusions drawn from this data. In addition, according to modeling estimates (including partition modeling of concentrations in shallow tidal water from sediment pore water data), low residues of imidacloprid or its degradates in overlying water, as well as pore water, can persist weeks after applications. Therefore, there is uncertainty in the comparison of the overlying water and pore water concentrations over time related to aquatic invertebrate toxicity. Aquatic invertebrate taxa represent the base of the food chain, and impacts on these taxa will likely cascade up the food chain, resulting in a reduction in prey and modification of PCE's related to endangered species due to fewer prey, as highlighted in the conceptual diagram in **Figure 1**. Additionally, direct effects on these individual organisms, including crab species, can also be expected. Recruitment of other individuals to on-site locations following removal of the shrimp may be a significant pathway of recovery for the impacted taxa. However, the submitted biotic monitoring data indicate potential decreases in abundance for crustaceans and polychaetes at least 28 days post application without evident recovery, although these results are uncertain as well because the data are partial or incomplete and have not been formally submitted for review. Nonetheless, the submitted biotic monitoring data support the aquatic invertebrate risk conclusions contained in this assessment.

While EFED recognizes that acute mortality in the immediate application site may be very high for aquatic animals trapped in tide pools and/or living in benthic sediments, the potential for off-site effects and overall impact to Willapa Bay as a whole appears limited. This is based on estimates that roughly 10% of the total acres (79,000 total acres) of the bay are under shellfish production during any given year, the label allows only one application per year, relatively low or non-detectable residue levels at 30ft off-site, and that during a complete tidal cycle (low tide to high tide), as much as 25.4 million ft^3 of water (up to 45% of the bay's total volume) may be exchanged. Thus, the opportunity for dilution alone is significant. Although this discussion has focused primarily on Willapa Bay, it is believed that the same potential for dissipation exists for Grays Harbor where a similar percentage of the total acreage may be treated. However, EFED also notes that the potential acreage to which imidacloprid will be applied may increase if

recruitment rates of ghost and mud shrimp increase. Sustained increases in the acreage treated may be accompanied by increases in the spatial extent of consequent long-term impacts to the aquatic invertebrate assemblage (and an increased potential for indirect effects to taxa that depend on these invertebrate species) for the following reasons:

- The persistence of imidacloprid in sediment pore water for weeks after the initial application
- The sensitivity of certain marine taxa to imidacloprid
- The results from the risk assessment showing acute and chronic LOC exceedances for estuarine free-swimming and benthic invertebrates
- The preliminary indication that chronic effects are possible that reduce abundance of polychaete and crustacean taxa on the site of application at least up to 28 days post application without apparent recovery
- Environmental fate studies in soil and soil-water systems indicate that imidacloprid residues may persist for hundreds of days following application suggesting that imidacloprid might remain present in the estuaries from year to year (even though concentrations in most collected samples fall below detection limits after only 1 year's application to limited acreage)

It is also important to note that these impacts are primarily on the site of application with little concern off-site. Uncertainty remains regarding the risk picture off-site due to yearly applications of imidacloprid to the same oyster beds, potential increases in the acreage to which imidacloprid will be applied, and the persistence of imidacloprid residues in the sediment pore water where the concern is that residues may remain available or increase off-site over time. Consequently there is uncertainty in the spatial extent of the residues and potential impacts off-site.

In terms of terrestrial taxa, risk is only present for the flowable formulation but not the granular formulation. For the granular formulation (Protector 0.5G), the avoidance behavior exhibited by birds, the unlikely consumption of granules by larger mammals feeding in the mudflats, and the requirement that the granules dissolve on the mudflats to lead to surface residues leads EFED to conclude that the granular use on exposed or inundated mudflats will not pose a risk concern for terrestrial taxa. For the flowable formulation (Protector 2F), EFED found no risk to mammals, and the risk to birds appears to be for applications of Protector 2F at low tide to exposed mudflat surfaces. Similarly, the concern for terrestrial invertebrates other than bees also relates to the same application of Protector 2F to exposed mudflat surfaces. In summary, only applications of Protector 2F to exposed mudflat surfaces with or without vegetation (*e.g.*, eelgrass) pose a risk concern to terrestrial taxa, but this risk persists for a relatively short amount of time as inundation is expected to rapidly dilute the residues of imidacloprid. Based on preliminary data, this risk concern could be addressed by limiting applications of Protector 2F to periods when there is standing water over the mudflats. The data do not definitively answer the question of how much water should be on the bed though because measurements on eelgrass were not taken at various times immediately after application, but rather at 24 hours after application at the earliest time. The additional monitoring data that have yet to be submitted to the Agency may address this question.

Additional Data Needs

There are a number of uncertainties that translate into data needs related to the proposed use of imidacloprid on shellfish beds in Willapa Bay and Grays Harbor. There is uncertainty related to actual exposure levels *in situ* at both on-site and off-site locations in pore water, sediments, and overlying water. Furthermore, while preliminary data has been submitted to the Agency regarding effects to the biotic community at on-site and off-site locations, additional data are needed to evaluate the potential for long-term effects to the biotic community. EFED anticipates that final reports for both the 2011 and 2012 seasons will be submitted to the Agency for review. These reports should include sampling of vegetation, pore water, sediment, overlying water, and biotic community metrics at on-site and off-site locations. In addition to these EUP data, additional monitoring of concentrations over time in Willapa Bay and Grays Harbor would also help to address the uncertainty related to the persistence of imidacloprid and possible long-term concentrations in sediments. This additional monitoring may be addressed through the NPDES permitting process with the State of Washington. The monitoring data collected as part of the NPDES program should then be submitted to the Agency for review. These reports and additional data would provide a basis for further evaluating the conclusions in this assessment and assist EFED to confirm or eliminate potential concerns from the risk conclusions identified in this assessment.

Another area of uncertainty relates to the degradates and their toxicity to fish. Current EcoSAR estimates of toxicity from EPISUITE poorly estimate toxicity levels of parent imidacloprid, and may therefore be providing poor estimates of the degradates as well. It appears that EPISUITE is underestimating the toxicity of the parent imidacloprid by two orders of magnitude. If this same margin of safety (two orders of magnitude) is applied to the degradates of concern, the desnitro olefin, desnitro (guanidine), and urea degradates remain a potential concern. At present EFED has not identified data on the desnitro olefin degradate and its rate of formation relative to the parent. Concerning the other two degradates, preliminary pore water data suggest that the urea and desnitro (guanidine) metabolites are likely forming. Monitoring data to be submitted from 2011 and 2012 EUP studies may address this uncertainty if levels of the chronic total residue levels in overlying water are undetectable. However, if the monitoring data reveal that these degradates form at relevant levels or if no data on these degradates are available, then additional toxicity information for these three degradates to saltwater fish would address this uncertainty. An acute toxicity test with sheepshead minnow (850.1075) using the appropriate degradates would provide an initial comparison with the parent compound. If the degradates appear to be more toxic than the parent compound, additional chronic testing (850.1400) may be warranted.

Problem Formulation

Commercial shellfish beds in Willapa Bay and Grays Harbor, Washington, are important sources of shellfish production in the United States. In order to maintain the productivity of these beds for shellfish production, growers need to control various species of burrowing shrimp. Two native crustacean species, the ghost shrimp, *Callianassa* sp., and the mud shrimp, *Upogedia* sp., burrow into the sediment of the bays and disturb shellfish habitat (Felsot and Ruppert, 2002)[1]. To date, these burrowing shrimp have been managed using applications of carbaryl. However, the voluntary phase-out of carbaryl use in these estuarine habitats for controlling the burrowing shrimp has provided the impetus for the search of an alternative means of controlling these shrimp.

In response to this search, the Oyster Growers Association of Willapa Bay and Grays Harbor have explored the use of imidacloprid on these commercial shellfish beds. Small scale research trials were initiated in 2005 to explore the efficacy of imidacloprid to control burrowing shrimp. Then in 2008 through 2012 large scale trials were conducted not only to evaluate the efficacy of imidacloprid but also to explore the fate of the chemical in the estuarine systems and the potential for adverse effects to the ecological integrity of the biological communities. Monitoring of residues and effects data from these past studies have been submitted to the Agency through 2010; however, only a summary of the 2011 monitoring data and none of the 2012 data from the most recent experimental use permits have been submitted to the Agency for review. When available, analysis of the additional data for 2011 and 2012 might provide an improved understanding of imidacloprid environmental fate and effects under the conditions of this use.

Following the conduct of these large scale studies under the experimental use permits, IR4 requests registrations for the uses of Protector 2F and 0.5G (imidacloprid as the active ingredient) for the control of ghost and mud shrimp. The proposed labels for Protector 2F (flowable concentrate) and 0.5G (granular) allows for an application of imidacloprid at 0.5 lbs a.i./acre per year.

Willapa Bay is located on the Pacific coast of Washington State and encompasses 79,000 acres at mean high tide representing a volume of 56.6 million ft^3 of water. The tidal range in Willapa Bay is from 14 to 16 feet and roughly 45% (25.4 million ft^3) of the water in the bay is exchanged into the Pacific Ocean during a complete tidal cycle. The relatively shallow bay has more than 50% of its acreage exposed at low tide with much of the remaining surface area, except for channels, covered by 1 to 6 feet of water. Channel depths range from 30 to 50 feet with maximum depths 75- to 77-ft below mean low water. Willapa Bay opens to the Pacific Ocean at its northwestern corner through a broad shallow pass about 6 miles wide between Cape Shoalwater and Leadbetter Point. Major tributaries to the bay include the Willapa River to the north and the Naselle River to the south, together draining an area of 461,280 acres in Pacific County, Washington. Rainfall in the Willapa Bay area ranges from 85 - 100 inches per year resulting in mean annual runoff for the entire basin of 3.4 million acre-feet; mean maximum discharge at the

[1] Felsot, A.S. and J.R. Ruppert. 2002. Imidacloprid residues in Willapa Bay (Washington State) water and sediment following application for control of burrowing shrimp. J Agric. Food Chem. 50:4417-4423.

mouth of Willapa Bay is estimated at 1.6 million ft^3/second. Mean daily runoff is estimated to be about 0.004% of the total volume of the bay (Hedgpeth, J. W. and S. Obrebski 1981. Willapa Bay: A Historical Perspective and a Rationale for Research. Coastal Ecosystems Project, Office of Biological Services, U. S. Fish and Wildlife Service FWS/OBS-81/03).

The entrance of Willapa Bay is approximately 28 miles north of the mouth of the Columbia River and approximately 11 miles south of the entrance to Grays Harbor. Flushing rates (tidal prism) in Willapa Bay are influenced by conditions in the ocean. During the summer, strong northwesterly winds bring upwelled water from the ocean into the bay and promotes rapid turnover. Strong Pacific storms also promote mixing. At other times though, freshwater outflow from the Columbia River acts as a discrete water mass moving northward along the Pacific coast and may prevent mixing from occurring in the bay (Hedgpeth and Obrebski 1981).

Imidacloprid {1 - ((6 - chloro - 3 - pyridinyl) methyl) - 4,5 - dihydro - N - nitro - N - nitro - 1H - imidazol -2-amine} is a systemic neurotoxic insecticide of the nitroguanidine chemical class (chlorinated derivative of nicotine). As a neuron effector, this compound attacks the cholinergic receptors, especially the nicotinic receptors, by out-competing acetylcholine for available binding sites, thereby rendering acetylcholine dysfunctional. In terrestrial systems, given its systemic properties in a plant, it typically kills feeding insects via ingestion or contact by disrupting the nervous system. In these estuarine systems, the imidacloprid may act by causing acute mortality or immobilization to the ghost and mud shrimp.

In light of the proposed use pattern on shellfish beds and direct application to the aquatic environment in estuarine systems, EFED focused its assessment primarily on the potential harm to aquatic organisms. The aquatic species exposure assessment did not directly use the PRZM/EXAMS model normally used for such assessments as it has not been designed to evaluate pesticide fate in estuaries / intertidal / subtidal waters. Rather, we used monitoring data already available for this use as well as conservative (protective) assumptions regarding imidacloprid fate in this environment with the understanding that imidacloprid behavior may be different in some ways in estuarine environments. Exposures in sediment pore water and in standing water directly over and near the application area were assessed. The surface / pore water assessment for this compound takes into consideration the proposed label, use patterns, application rates and methods of application. Data submitted from the Oyster Growers Association and data provided by the registrant (e.g., environmental fate and effects), and information gleaned from peer reviewed open literature, were all used to support the risk characterization. In order to evaluate potential concerns to birds and mammals that feed on exposed prey items, EFED also assessed birds and mammals that fed on contaminated prey using the Kow (based) Aquatic Bio-Accumulation Model (KABAM) as well as TREX using the contaminated arthropod data.

Although EFED does not conduct risk assessments on beneficial insects, available toxicity profiles (e.g., honey bee oral and contact toxicity studies), incident reports and proposed use patterns are taken into consideration in order to arrive at a best professional judgment as to potential risk to these organisms. The potential for direct toxic effects to honey bees is minimal given the low likelihood of exposure from the use pattern on oyster beds. However, EFED assessed potential effects to terrestrial invertebrates that may inhabit the tidal mudflats after

applications of imidacloprid.

The representative aquatic receptors are certain estuarine/marine fish, invertebrates, and, in certain cases, aquatic plants. The representative terrestrial receptors are mammals, birds, and invertebrates that feed in the intertidal mudflats where commercial shellfish are produced. It should be noted, that these species do not cover all the possible species in the animal and plant kingdoms; certain taxa are considered as surrogates for other taxa. Fish are considered surrogates for aquatic amphibians and reptiles, whereas birds are considered surrogates for terrestrial amphibians and reptiles.

The major point of exposure for aquatic organisms is direct contact with contaminated water or sediments (gill/ integument uptake), while for terrestrial invertebrates it is primarily through contact exposure to contaminated substrate. For terrestrial vertebrates, the primary routes of exposure are consumption of contaminated food items. A conceptual diagram (**Figure 1**) shows that various routes of exposure.

Risk Hypothesis:

The insecticide imidacloprid as proposed as a spray and granular product on shellfish beds involves situations in the environment where direct contamination of bodies of water are potential routes of exposure to aquatic taxa. Furthermore, these applications may result in exposure to terrestrial animals that feed on contaminated food items, come into contact via dermal exposure, or that may directly consume granules on the sites of application. Based on imidacloprid's persistence, mode of action, direct toxicity and potential indirect effects to trophic food webs, it is assumed that this compound may have the potential to cause reduced survival and possible reproductive impairment to both aquatic and terrestrial organisms on estuarine tidal mudflats in Grays Harbor and Willapa Bay, Washington.

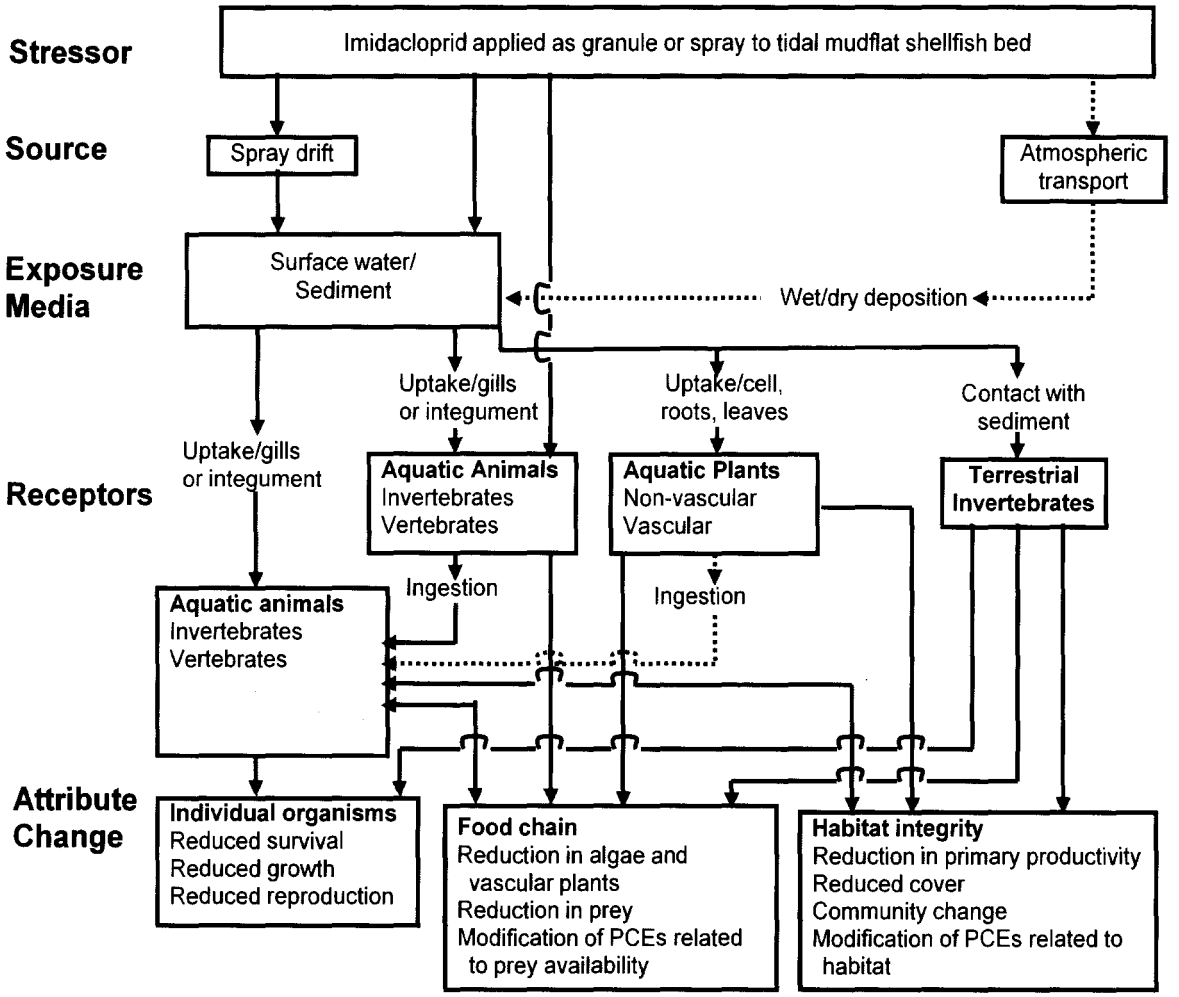


Figure 1. Conceptual model for the exposure pathway to aquatic organisms and terrestrial organisms that use the shellfish mudflats at low tide. Dashed lines represent pathways not considered to be significant due to the use pattern or chemical nature of imidacloprid.

Exposure and Effects Analysis

Analysis is a process that examines the two primary components of risk, which are exposure and effects, and their relationships between each other and site characteristics. The objective is to provide the ingredients necessary for determining or predicting ecological responses to pesticide use under exposure conditions of interest. The products of analysis provide the basis for estimating and describing risks in risk characterization.

Label Information

Product Names and Reg. Nos.: *Protector 2F (88867-E) and 0.5G (88867-R)*

Composition
Protector 0.5G
Imidacloprid (a.i.) 0.5%
Inerts 99.5%

Protector 2F
Imidacloprid (a.i.) 21.4%
Inerts 76.6%

Formulation and Use:
Protector 0.5G is a granular formulation of imidacloprid to be applied at a rate of 0.5 lb a.i./A as a single application per year, which must occur between April 15 and December 15. This product will be applied to control burrowing shrimp in intertidal shellfish beds of Washington State's Willapa Bay and Grays Harbor. Application equipment includes conventional granular pesticide applicators ("belly grinders"), helicopters equipped with a boom ¾ as long as rotor diameter, or a ground based vehicle equipped with spinners or drop spreaders. Aerial applications must be on beds exposed at low tide. Applications from a floating platform or boat may be applied to beds under water using a calibrated granular applicator.

Protector 2F is a flowable formulation containing 2lbs of imidacloprid per gallon of product to be applied at a rate of 0.5 lb a.i./A as a single application per year, which must occur between April 15 and December 15. This product will also be applied to control burrowing shrimp in intertidal shellfish beds of Washington State's Willapa Bay and Grays Harbor. Application equipment includes helicopters equipped with a boom ¾ as long as rotor diameter and equipped with Accuflo or similar nozzles, or a backpack sprayer, or ground based vehicle with a boom. A single application per year is allowed. Aerial applications must be on beds exposed at low tide. Applications from a floating platform or boat may be applied to beds under water using a calibrated granular applicator.

Label Warnings
The following environmental hazards statements are currently on the proposed labels for 0.5G and Protector 2F:

Protector 0.5G: *Do not contaminate water when disposing of equipment washwaters. This product is toxic to wildlife and highly toxic to aquatic invertebrates.*

Protector 2F: *Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops and weeds. Do not allow this product to drift to blooming crops or weeds are visiting the treatment area. This product is toxic to wildlife and highly toxic to aquatic invertebrates.*

Environmental Fate Summary

Imidacloprid degrades most rapidly when subjected to aqueous photolysis and/or anaerobic aquatic metabolism. Imidacloprid appears to be stable (persists for several months or more) to aerobic soil metabolism. The chemical is mobile and because it is also highly persistent, is a major concern for groundwater where there have been detections. Its transformation product imidacloprid guanidine / desnitro may also leach to groundwater. Imidacloprid may readily runoff dissolved in water and reach adjacent bodies of water. Since the chemical appears to be persistent under aerobic soil metabolism, imidacloprid may be available for runoff for periods exceeding one season.

It appears that photolysis plays an important role in the environmental dissipation of imidacloprid if it is exposed to sunlight, both in aqueous solution (half-life 0.2 days) and on soil (half-life 39 days). In aqueous solution, the degradates imidacloprid guanidine / desnitro (17% at 2 hours; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}) and imidacloprid urea (10% at 2 hours; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinone.{NTN 33519}) were observed. However, the length of the study did not allow for observation of the stability of the degradates; furthermore, there is uncertainty regarding this study because other laboratory studies were performed under sunlight and no extensive degradation of the parent was observed. Another route of transformation that appears to be important for imidacloprid is anaerobic aquatic metabolism (half-life 27 days), with the formation of imidacloprid guanidine / desnitro (66% at 249 days; 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}), a compound that appeared to be very persistent.

In a domestic sandy loam, and foreign loamy sand, silt loam, and sandy loam, imidacloprid proved to be very persistent under aerobic soil metabolism conditions. The respective half-lives were 660, 188, 248 and 341 days. No major transformation products were detected in these studies.

Imidacloprid has K_{OC}s ranging from 161 to 256 (based on nine soils, five domestic and four foreign). The K_{ads} range is 0.96-4.76 for the same nine soils. Imidacloprid guanidine / desnitro is somewhat less mobile than the parent imidacloprid (K_{OC} range 327-942; K_{ads} range 0.76-14.20).

Due to the very low octanol/water partition coefficient of imidacloprid, it is not expected to bioaccumulate in fish and the data requirement was waived. .

Five terrestrial field dissipation studies confirm the findings in the laboratory, that under aerobic soil metabolism conditions, imidacloprid persists substantially. The dissipation half-lives from topsoil were as follows: >365, >>365, 146, 107, and >120 days.

Small scale prospective ground water monitoring (PGW) studies in Michigan and California have been conducted, and while not necessarily representing field conditions under which ground water recharge and imidacloprid leaching would be greatest, do provide some information on imidacloprid leaching and ground-water contamination potential. Imidacloprid and some of its degradates were shown to leach in soil during water infiltration periods at both

study sites.

The California study appears to include some effects of nearby applications of imidacloprid in years prior to the initiation of the study, with control samples bearing imidacloprid residues. At the California site only a few ground-water detections of imidacloprid and its degradates have been reported at concentrations between 0.05 and 0.10 ppb. The study does demonstrate that imidacloprid may leach substantially under conditions of irrigated agriculture for vegetable crops in California.

In the Michigan study (planted to potatoes), imidacloprid (applied once at a 0.34 lb a.i./A rate) leached at a variable rate and concentration. Detectable residues of imidacloprid occurred in six out of six, and in four out of six on-site lysimeters at the three and six foot depths, respectively, by 319 days after treatment (DAT 319), at concentrations up to 3.35 ppb.

At the Michigan study site, imidacloprid parent was consistently detected in one of six monitoring well clusters in the treated field beginning about 500 days after application and continuing through the close of the study some 5 years after application. No degradation products were detected in ground water during this period (there were a few detections before application that may have been due to previous uses nearby or sample contamination). The maximum concentration of imidacloprid parent detected in ground water in any one sample at the Michigan study site was 0.24 ppb. EPA concluded that the 0.24 ppb level might increase slightly over time as imidacloprid continues to leach into groundwater; however, the level was not expected to increase dramatically given that the levels seen at the three and twelve foot soil depths was 1.63 ppb and 1.31 ppb, respectively.

Data from the California site is less useful due to the fact that there appears to have been very little ground-water recharge occurring during the course of the study as evidenced by the almost complete lack of detection of the bromide tracer (applied concurrently with imidacloprid) in ground water. The maximum combined residue of imidacloprid parent and degradates found in the suction lysimeters was 0.62 ppb at 633 days post application (made once at a rate of 0.45 lb a.i./A). The maximum combined imidacloprid residue in the ground water at the California site was 0.14 ppb found 149 days post application. EPA concluded that low (sub-ppb) level contamination of potable ground water might occur in this region following application to irrigated vegetable or fruit crops.

Other significant ground-water monitoring data[2] include evidence of leaching of imidacloprid from New York state monitoring. Suffolk County Department of Health Services reported that there were 27 detections of imidacloprid above a detection limit of 0.2 ppb in about 5,000 samples.[3]

---

[2] An updated review of the available monitoring data may be conducted if a permanent registration of this new use is sought.

[3] Electronic mail communication from Sy Robbins, Suffolk County Department of Health Services, Bureau of Groundwater Resources), 1/16/2004 to Michael R. Barrett, (US EPA, Office of Pesticide Programs Environmental Fate & Effects Division). See also:

More recently, imidacloprid has been detected in several domestic drinking water wells in New York State:

> "To date, imidacloprid has been detected at concentrations (0.2 to 7 ppb) in 12 monitoring wells and 16 down gradient private homeowner wells. Imidacloprid has also been recently detected at 0.24 ppb in two Suffolk County community water supply wells (85 feet and 90 feet deep)." (Imidacloprid NYS DEC Letter - Registration of New Imidacloprid Products in New York State as Restricted-Use Products 10/04)

Not all of the imidacloprid detections in drinking water wells, however, necessarily represent normal leaching from an imidacloprid-treated field (See **Appendix A** for details).

In a small turf plot surface water runoff monitoring study by the registrant, the plot received from 1.7 to 3.5 in. water per hour for two hours. Up to 20% of the applied imidacloprid was found in runoff water 24 hours after application.

Fate Assessment for Exposure Modeling

Imidacloprid is stable to hydrolysis, and typically persists for many months in soil. However, imidacloprid appears to be more rapidly transformed under anaerobic conditions and appears to be particularly photolabile in pure, clear, shallow water. Given that imidacloprid is mobile, and likely to be highly persistent in the subsurface, it may leach to ground water (results of the prospective ground-water monitoring studies confirm this). Imidacloprid may also pose a contamination hazard to surface waters via runoff, and may be especially persistent in surface water with high turbidity.

The environmental fate for imidacloprid is discussed in more detail in **Appendix A**.

EFED concludes that the available data on imidacloprid show that the compound is mobile and persistent, and, for the terrestrial uses, has potential to leach to ground water, and to be transported to surface water by runoff. In the context of the proposed use in estuaries, the available fate data would seem to indicate that at least some portion of the applied imidacloprid may be adsorbed to sediment and resistant to long-term degradation (similar to what has been observed in terrestrial field dissipation studies. However, no studies are available on the fate of imidacloprid in salt water / estuaries. No direct environmental fate studies have been conducted for the degradates {several of which retain the (pyridinyl)methyl-imidazoli-amine backbone of

---

Bradley, Clare B.; Vito Minei, and Martin Trent. 2002a. *Golf course impacts to shallow groundwater: Suffolk County, NY.* Suffolk County Dept. of Health Services & Bureau of Groundwater Resources report received in a personal communication from Martin Trent, February, 2004. (No report number assigned).

Bradley, C.B.; V. Minei, and M. Trent. 2002b. *Impacts of agriculture on shallow groundwater in Suffolk County, NY.* Suffolk County Dept. of Health Services, no document or report number assigned.

Bradley, C.B.; V. Minei, M. Trent, and S.F. Robbins. 2003. Water quality monitoring program to detect pesticides in groundwaters of Nassau and Suffolk Counties, NY: Monitoring conducted April 2001 - March 2002. Suffolk County Dept. of Health Services, no document or report number assigned.

the imidacloprid molecule}, including the following (potentially) major environmental degradates typically found under aerobic conditions: 1) imidacloprid guanidine / desnitro, 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinimine {Alias NTN 38014, NTN 33823}; 2) imidacloprid olefin, 1-[(6-chloro-3-pyridin1yl)methyl]-1,3-dihydro-2H-imidazol-2-imine {NTN 35884}; and 3) imidacloprid urea, 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinone{NTN 33519}. Under anaerobic conditions, imidacloprid is reduced to the guanidine / desnitro and then to 6-Chloronicotinic acid {BNF 5518A}[4]. See **Appendix B** for chemical structures of these degradates. Another metabolite of imidacloprid in some biological systems and of some toxicological concern (discussed later in this review), imidacloprid nitrosiamine, has not been reported to any significant extent in environmental fate studies.

Terrestrial Exposure Estimation

Measures of exposure for terrestrial invertebrates directly exposed to spray applications or mammals and birds that feed on plants or invertebrates in the tidal mudflats incorporate maximum proposed use rates, but rely less on environmental fate properties. Terrestrial exposures were estimated using a number of methods. The Kenaga nomogram, as modified by Fletcher *et al.*, (Kenaga and Hoerger 1972; Fletcher *et al.* 1994) is used to relate pesticide application rates to chemical residues on terrestrial food items. The surface residue concentration (in parts per million; ppm) is estimated by multiplying the application rate (pounds active ingredient per acre; lbs a.i./A) by a value specific to each food item. The Terrestrial Exposure (T-REX; version 1.5.1) model is used with the maximum application rates on the proposed labels. Acute exposure is the only type of exposure considered in this assessment so degradation is not considered because of the tidal nature of the system. Tides remove much of the residues considering the solubility of imidacloprid. The conceptual approach taken to estimate residues (upper-bound and mean) in potential dietary sources for mammals and birds is presented in the model T-REX Version 1.5.1 available at:

http://www.epa.gov/oppefed1/models/terrestrial/index.htm

In addition, the model KABAM (Kow(based) Aquatic BioAccumulation Model, ver.) was used in this assessment to quantitatively assess the risk of imidacloprid to birds and mammals that feed on aquatic food sources contaminated through bioaccumulation. While imidacloprid has a very low Kow, which suggests very low potential exposure levels, KABAM provides a quantitative confirmation of the risk expectations. Details on KABAM Version 1.0 are available at:

http://www.epa.gov/pesticides/science/models_pg.htm#aquatic

Aquatic Exposure Estimation

In this assessment, measures of exposure are made with a combination of analysis of available imidacloprid residue monitoring data and assumptions on degradation and partitioning rates from

[4] Preliminary information from MRID 48416901 (Wilmes, R. 1988. Aerobic aquatic metabolism of NTN 33893); study is still under review, however. Imidacloprid guanidine / desnitro was the dominant primary degradate in studies from both MRID 42256378 and MRID 48416901.

the available environmental fate data (there are only a limited amount of such data, however, directly examining imidacloprid fate in salt water). Generally, aquatic exposure estimates are generated from EFED models and incorporate maximum proposed use rates and empirically-derived fate properties. However, currently approved aquatic exposure models for EFED (e.g., PRZM-EXAMS, GENEEC) are not designed to estimate exposure in estuarine environments. Partitioning theory that is incorporated into such models was used along with the available environmental fate data to conservatively estimate exposure of organisms to imidacloprid residues in both sediment pore water and tidal flood waters. Additional details on exposure estimation procedures and model inputs and outputs are provided in **Appendix C**.

A summary of model input parameters for imidacloprid used in the modeling is provided in **Table 1**. Exposure to degradates was also estimated, but only as part of the total imidacloprid residues. Estimation of exposure to individual degradates (like the potentially more toxic desnitro olefin as based on EcoSAR estimates) is not feasible given that both environmental monitoring and fate data are limited in terms of capturing the full extent of formation and decline of the degradates. However, for the two degradates of potential toxicological concern, the available fate data imply that, except in anaerobic sediments/soils, the olefin could potentially be a major component of exposure over time whereas the nitrosamine would likely not be (except for organisms consuming other organisms which have already converted imidacloprid to the nitrosamine.)

Table 1. Imidacloprid parent environmental fate parameters utilized in oyster bed exposure assessment.

Parameter	Input	Source
Solubility (ppm)	580	Product chemistry submissions
Hydrolysis $t_{1/2}$ @ pH 7 (days)	Stable	MRID 42055337
Aerobic soil $t_{1/2}$ (days)	520	MRIDs 452393-01, 02, 42073501; 90% upper bound confidence limit of mean
Aerobic aquatic $t_{1/2}$ (days)	165 (prelim.)	MRIDs 48416901 and 48416902; 90% upper bound confidence limit of mean (preliminary value – studies are still in review.)
Photolysis $t_{1/2}$ in soil or water (days)	39 (soil) 0.2 (water)	Input guidance & MRIDs 42256376; 42256377; the longer soil photolysis values is considered more relevant to this assessment because of persistence in irradiated water in ecotoxicity studies (inconsistent with a 0.2 day $t_{1/2}$ value) and limited exposure of imidacloprid molecules to sunlight from the oyster bed use.
Organic carbon partition coefficient		

- K_d (mL/g)	0.5, 1.0, or 3.0	MRIDs 425208-01 and 420553-38 and Felsot and Ruppert (2002).
Application rates (lb a.i./Acre)	0.5	Maximum on proposed label.
Applications / year Oyster Beds	1	Maximum on proposed label.

Sediment Pore-Water Exposure.

Acute and chronic (for durations up to 35 days) estimated environmental concentrations (EECs) for benthic invertebrates and other organisms feeding in areas where they would be exposed to concentrations in the sediment pore water are presented for the granular and flowable formulations in **Table 2** and **Table 3**, respectively. These time-weighted exposure estimates are based upon 90th percentile upper bound confidence limits of the mean concentrations detected over time in a 2010 monitoring program for the Oyster Growers Association of Willapa Bay and Grays Harbor, adjusted for the currently proposed maximum application rates and other factors. The total residue estimates conservatively assume that all of the residues detected with the enzyme-linked immunosorbent assay (ELISA) analysis represented degradation products of imidacloprid such as imidacloprid olefin, desnitro imidacloprid (guanidine degradate), or imidacloprid urea which have been shown to be detectable by the method used.

For the flowable formulation the initial concentrations detected in the soil pore water after application were close to theoretical concentrations assuming all of the applied imidacloprid was in the top 10 cm of sediment pore water (the sampling depth used). For the granular application the concentrations were significantly below expectations. The slower release of imidacloprid from the granular formulation may have contributed to the lower concentrations detected initially, but it is also true that observed concentrations continued to be lower from the granular application than from the flowable application over time.

Table 2. Estimated ecological concentrations (EECs) in ppb for Imidacloprid in soil pore water: Oyster bed, proposed IR4 use (0.5 lb a.i./ A rate, granular formulation.)

Moiety	Crop Scenario	Peak (theoretical)	Peak (measured)	Acute (24-hour)	21-day	35-day
Parent	Oyster Bed On-site	1252.5	221.2	97.0	9.9	6.3
Total Residues	Oyster Bed On-site	1252.5	221.2	97.0	30.8	19.7
Total Residues	Oyster bed off-site*	NC	0.8	0.8	0.5	0.4
Values in this table are time-weighted average exposure levels for the specified duration of exposure based upon time weighting upper bound Confidence Limits of mean of on-site or off-site detections at each sampling interval. For off-site chronic exposure, residues at just below the limit of detection were assumed when no detections were reported						

Table 3. Estimated ecological concentrations (EECs) in ppb for Imidacloprid in soil pore water: Oyster bed, proposed IR4 use (0.5 lb a.i./ A rate, flowable formulation).

Moiety	Crop Scenario	Peak (theoretical)	Peak (measured)	Acute (24-hour)	21-day	35-day
Parent	Oyster Bed	1252.5	1066.4	416.8	34.3	21.8
Total Residues	Oyster Bed	1252.5	1066.4	416.8	107.1	68.1
Total Residues	Oyster bed off-site*	NC	2.0	2.0	1.6	ND

Values in this table are time-weighted exposure levels for the specified duration of exposure based upon time weighting upper bound Confidence Limits of mean of on-site or off-site detections (proportionally adjusted from the original 2.0 to a 0.5 lb a.i./A application rate) at each sampling interval.

The significant decrease in chronic EECs from acute EECs reflects a rapid decline in the observed concentrations over time (see **Table 4**, which shows the decline in point-in-time concentrations up to 28 days after the flowable application). This decline rate likely only partially reflects degradation and could be largely a function of dispersion of imidacloprid (since the available environmental fate data indicate imidacloprid parent may persist for several months or longer in the environment). Imidacloprid metabolites appear to represent an increasing percentage of the residues detected in the later times [based on preliminary data comparing HPLC (high-performance liquid chromatography) and ELISA (the enzyme-linked immunosorbent assay) analyses submitted by the registrant, a complete report has not yet been submitted].

Table 4. Instantaneous measured and estimated concentrations over time in ppb for Imidacloprid in soil pore water: Oyster bed, proposed IR4 use (0.5 lb a.i./ A rate, flowable).

Moiety	*Crop Scenario*	*0 (theoretical)*	*0 (measured)*	*1 DAT*	*14 DAT*	*28 DAT*
Parent	Oyster Bed	1252.5	1066.4	40.1	3.9	3.1
Total Residues	Oyster Bed	1252.5	1066.4	40.1	12.1	9.7
Total Residues	Oyster bed off-site*	NC	1.3*	0.8	0.12	<0.1

All values are 90 percentile Upper Confidence bound of mean of detects at the specified time interval.
Off-site values are 90 percentile Upper Confidence Limit of mean of quantifiable detects 30 feet from the treatment area (either up- or down-gradient.) Original monitoring data were from a 2.0 lb a.i./A application; the values were adjusted proportionally downward to compare with the proposed 0.5 lb a.i./A maximum application rate.
* Value at 12 hours after application; residues not detectable at 30 feet off-site at the time of application. The highest single detect 30-feet from the treatment area.

Standing-Estuarine Water Exposure

Data on imidacloprid residues in standing tidal water over and near oyster beds are limited but tend to show low to nondetectable imidacloprid residues within a few hours or days after

application. However, there are some important factors that limit the ability of such sampling to accurately capture all residues remaining at the site:

- Residues of imidacloprid tend to increasingly associate with adsorbing materials in the sediment. Some of these residues may become "bound" and will not be detected except with particularly vigorous means to extract them.[5]
- Most studies do not include analyses of all degradates, which might contribute to imidacloprid toxicity to some organisms (cross-reactivity of the ELISA method with degradates formed over time might account for the relatively high chronic exposure estimates obtained from the 2010 soil pore water sampling program for the WGHOGA).

In order to assess the exposure potential of aquatic organisms present in shallow standing tidal water areas, we incorporated partitioning theory used in existing EFED aquatic exposure models (PRZM-EXAMS, GENEEC). Details of the procedure for these estimates are provided in **Appendix C**.

A comparison of directly measured concentrations of parent imidacloprid (specific monitoring data are not available for imidacloprid degradates) in standing tidal water from 2011 monitoring (HPLC analysis) with the calculated potential concentrations in standing water (based on distribution of the known concentrations in sediment pore water from the 2010 monitoring) is provided in
Table 5. This table provides insight into how modeling standing water concentrations compare with field measurements. Note that application rates in these studies may vary and that in some cases imidacloprid may have been present in field samples at levels below the reporting limit of the analytical method used. The modeled K_ds represent a range of potential adsorption coefficients for the sediment that are within the range of values previously reported for imidacloprid in soil[6]. Felsot and Ruppert (2002) examined the characteristics of sandy sediment in a small plot study of imidacloprid dissipation in Willapa Bay and found that it had a K_d of 0.37 and particle distribution of 84% sand, 15% silt, and 1% clay.
Table 5 shows the increasing trend in imidacloprid water concentrations when the sediment capacity to adsorb imidacloprid is lower (i.e., lower K_d), when the sediment mixing depth is shallower, and when the height of the standing water is shallower[7].

---

[5] See, for example:
Cox, L.; Koskinen, W.; Yen, P. 1998. Changes in Sorption of Imidacloprid with Incubation Time. Soil Science Society of America Journal 62(2): 342-347.
Koskinen, W.; Cox, L.; Yen, P. 2001. Changes in Sorption/Bioavailability of Imidacloprid Metabolites in Soil with Incubation Time. Bioi Fertil Soils 33: 546-550.
Papiernik, S.K., Koskinen, W.C., Cox, L., Rice, P.J., Clay, S.A., Werdin-Pfisterer, N.R., Norberg, K. 2006. Sorption-Desorption of Imidacloprid and Its Metabolites in Soil and Vadose Zone Materials. J. Agric. Food Chem. 54(21):8163-8170.

[6] Imidacloprid adsorption / desorption properties have been measured in eight soils in the registration guideline studies to support its registration (MRIDs 42520801 and 42055338). In these studies Kd values ranged from 1 to 5 with a large amount of the variation in adsorption associated with the variation between soils in percent organic carbon (the Koc values only varied between 132 and 256 for the eight test soils).

[7] The available sediment pore water monitoring data only provide overall concentrations of imidacloprid residues in the sediment to a depth of 10 cm, it is not known whether most of the imidacloprid residues were present to a depth substantially less than 10 cm, hence the use of the 3 cm mixing depth as a conservative modeling scenario which would result in predictions of higher standing water concentrations of imidacloprid residues than if the mixing depth

Table 6 presents a summary of acute and chronic EECs (for parent imidacloprid only) for organisms residing in the standing water for exposure durations from less than 1 day to 35 days (these are time-weighted exposure values whereas values in
Table 5 are point-in-time concentrations). A sediment K_d of 1.0 ml/g (lowest value in guideline batch equilibrium adsorption / desorption studies) was chosen for these estimates in finer sediment and 0.5 ml/g in sandy sediment, the latter based upon the published study by Felsot and Ruppert (2002). Calculation of time-weighted ecological exposure concentrations was based upon 3- to 10-cm depth standing water exposure estimates, providing a conservative estimate of exposure in the sense that average EECs in standing water will be lower than these estimates if concentrations were to be averaged over the entire tidal cycle. However, it is also not known whether pulses of higher exposure during the low water periods may be of similar toxicological significance to the steady exposure levels that are often used for testing of effects. The most conservative of the mixing assumptions for these estimates (i.e., that mixing of imidacloprid only occurs in a 3 cm deep band of sediment and that 3 cm of floodwater is the most relevant depth of standing water to calculate EECs) was used for acute and chronic EEC estimation.

Table 5. Comparison of measured and estimated concentrations over time in ppb for parent imidacloprid in standing water: Oyster bed, proposed IR4 use (flowable formulation, 0.5 lb a.i./ A rate, or adjusted for such a rate).

Site Info / Assumptions	K_d, ml / g	Sd. Mix. Depth, cm	H_2O Depth, cm	0-0.1 DAT	1 - 3 DAT	14 DAT	Reference
Finer sediment (estimated)	1	3	3	600.0	9.5 - 22.6	2.18	PRZM 3 manual
Finer sediment (estimated)	1	3	10	320.0	2.6 - 7.5	0.62	PRZM 3 manual
Finer sediment (estimated)	1	10	3	244.3	3.9 - 10.9	0.89	PRZM 3 manual
Finer sediment (estimated)	1	10	10	179.8	1.5 - 4.2	0.35	PRZM 3 manual
Loamy sand sediment (estimated)	0.5	3	3	871.8	13.8 - 38.9	3.17	PRZM 3 manual
Typical agric. Soil	3	3	3	267.6	2.2 – 6.3	0.52	PRZM 3 manual
2011 Cedar River – Flow.	2 hr sample with <10 cm water depth.			1100 - 1400	<1.5	----	2011 prelim. WGHOGA Rpt.
2011 Palix R. – Flowable	2 hr sample with 15 cm water depth.			4 - 89	<1.5	----	2011 prelim. WGHOGA Rpt.
2011 Cedar R. – Granular	0 hr sample with 30 - 90 cm water depth.			0 – 31	<1.5	----	2011 prelim. WGHOGA Rpt.
2011 Palix R. – Granular	2 hr sample with 16 cm water depth.			0 - 82	<1.5	----	2011 prelim. WGHOGA Rpt.

Source: Information sheet entitled "2011 Results Summary" (no author, report number, or other identifying information provided. Some of the results seem to be inconsistent with "preliminary" data provided in Moore and Tufts (2011).

---

was 10 cm. Further details are provided in Appendix D.

Table 6. Time-weighted acute and chronic EECs based on estimated concentrations of parent imidacloprid in shallow tidal water for acute and chronic exposure durations (flowable formulation, 0.5 lb a.i./A rate); assume sediment K_d of 1 ml/g (finer sediment) or 0.5 (sandy sediment).

Site Info / Assumptions	Sedimt. Mixing Depth, cm	Ref. Water Depth, cm	Peak	1-Day	4 -Day	21-Day	35 – Day
Finer sediment	3	3	600.00	231.00	102.95	21.79	14.81
Finer sediment	10	3	244.57	94.15	41.97	8.88	6.04
Sandy sediment	3	3	**871.75**	**335.61**	**149.59**	**31.66**	**21.53**

Other Surface Water Monitoring Data

An updated comprehensive review of all available surface water monitoring data was not practical for this review and we also note that these data are all for residues in freshwater as no estuarine uses have previously been registered for imidacloprid. Reports on imidacloprid surface water monitoring have increased in recent years as improved analytical methods have become more widely available. A number of reports have indicated low-level imidacloprid concentrations in surface waters (usually well under 1 ppb, although exposure might be higher in smaller bodies of water in small watersheds with intensive imidacloprid usage):

Byrtus, G., A. Anderson, K. Saffran, G. Bruns, and L. Checknita. 2002. Determination of new pesticides in Alberta's surface waters (1999-2000). The Water Research User Group, Alberta Environment. http://www3.gov.ab.ca/env/water/reports/NewPesticidesInSurfaceWaters_1999_2000.pdf

Environment Canada. 2006 (Draft). Presence, levels and relative risks of priority pesticides in selected Canadian aquatic ecosystems. Summary of 2003-2005 surveillance results. Prepared by Cantox Environmental for the National Water Quality Monitoring Office, Environment Canada, Ottawa.

Murphy,C., J.P. Mutch, D. Reeves, T. Clark, S. Lavoie, H. Rees, L. Chow, L-A. Nunn, and D. Hebb. 2006. Multi-media pesticide monitoring programs in Prince Edward Island, New Brunswick and Nova Scotia, Final Project Report of 3-year monitoring program, 2003/04 – 2005/06. Environment Canada, Environmental Protection Branch, Charlottetown.

Struger, J., T. Fletcher, P. Martos, B. Ripley, and G. Gris. 2002. Pesticide concentrations in the Don and Humber River Watersheds (1998-2000). Environment Canada, Ontario Ministry of the Environment, and City of Toronto. 21 pp.

USGS. 2007. Hydrologic, Water-Quality, and Meteorological Data for the Cambridge, Massachusetts, Drinking-Water Source Area, Water Year 2005. Open-File Report 2007–1049; Reston, VA.

Smith, Kirk P. 2011. Surface-Water, Water-Quality, and Meteorological Data for the Cambridge, Massachusetts, Drinking-Water Source Area, Water Years 2007–08. USGS Open-File Report 2011–1077.

Hladik, Michelle L. and Daniel L. Calhoun. 2012. Analysis of the Herbicide Diuron, Three Diuron Degradates, and Six Neonicotinoid Insecticides in Water—Method Details and Application to Two Georgia Streams. USGS Scientific Investigations Report 2012–5206.

Ecological Toxicity

The toxicity of imidacloprid to aquatic and terrestrial organisms is summarized below. More detailed information can be found in **Appendix D**. The available literature for ecotoxicity shows a nearly complete database for imidacloprid. In addition to these sources, a number of studies have been submitted to Europe and have been incorporated into the European draft assessment of imidacloprid[8]. The reviews from these studies have been used in this risk assessment, and the list of these studies are in **Appendix E**.

Aquatic (Acute/Chronic Hazard Summary)

Imidacloprid is considered to be practically non-toxic to fish (freshwater and estuarine/marine) on an acute basis (LC_{50} = 83 to 163 ppm). Chronic NOAEC/LOAEC values for freshwater fish were calculated at 1.2/2.5 ppm with growth being the major endpoint affected. However, toxicity studies on aquatic invertebrates (freshwater and estuarine/marine) show that this compound is acutely very highly toxic to these organisms (EC_{50} = 0.037 to 0.115 ppm). Chronic effects (growth and movement) were noted in daphnids (NOAEC/LOAEC = 1.8/3.6 ppm) and in mysid shrimp (NOAEC/LOAEC = 0.0006/0.0013 ppm). It is therefore evident that aquatic invertebrates are the taxa of concern related to aquatic exposure.

In data submitted to EFSA[9] but not to the US EPA, there are other endpoints worth noting. The EFSA assessment identifies a 28 day water spiked study with the benthic invertebrate *Chironomus riparius* with both the TGAI and a formulated product. The TGAI showed an EC_{15} of 0.00225 ppm, and the formulated product showed an EC_{15} of 0.0027 ppm. Consequently, benthic invertebrates appear to be very sensitive to chronic exposure to imidacloprid. There is uncertainty in these endpoints though, because the Agency typically uses a no effect level as opposed to the EC_{15} that is regression based. In addition, it is unclear how these endpoints relate to saltwater benthic invertebrates. A NOAEC is available from the midge acute toxicity study that the registrant has already submitted to the Agency and exhibits the lowest endpoint of 1ppb based on survival. It is important to note that this endpoint is based on a study evaluating acute exposure as opposed to the effects related to chronic exposure. However, since the Agency has not received the benthic invertebrate chronic exposure studies, these studies cannot be formally reviewed. Given the uncertainties related to the use of an endpoint from a water spiked study with a freshwater invertebrate and a chronic endpoint from an acute study, in addition to mysid shrimp appearing to be the most sensitive of all invertebrate taxa, the endpoint for chronic toxicity to mysid shrimp will be used for both free-swimming as well as benthic invertebrates that live in or on the sediment.

A number of studies with some of the degradates have been submitted to the Agency and are currently in review (MRIDs 43946601, 43946602, 43946603, 43946604, 44558901). These studies include acute toxicity data on the desnitro, urea, and 6-chloronicotinic acid to *Hyallela*

---

[8] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005. Table 2.6-6

[9] *Ibid.* Germany 2005.

azteca and/or *Chironomus tentans*. EFED has conducted a preliminary review of these studies, and these data show that the desnitro (guanidine), urea, and 6-chloronicotinic acid degradates are less toxic than the parent compound by at least over an order of magnitude. If the final reviews of these data provide additional information that alters the conclusions in this assessment, then EFED will revise its risk assessment as appropriate. Summaries of the studies are as follows:

- MRID 43946601: This study explored the acute toxicity of the desnitro/guanidine degradate to *Hyallela azteca*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the desnitro degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 5.3, 10.7, 21.4, 42.7, and 85.4 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *H. azteca* was used in the study and individuals were 0 to 7 days old when collected three weeks prior to study initiation, consequently they were 14 to 21 days old at test initiation. Mean measured concentrations reported in the study were 5.6, 11.0, 22.1, 43.8, and 86.8 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors observed the following mortality: 10% in the controls, 0% at the 5.6, 11.0, and 22.1 mg a.i./L levels, 30% at the 43.8 mg a.i./L level and 95% at the 86.8 mg a.i./L level. Sublethal effects were found at the 11.0, 22.1, 43.8, and 86.8 mg a.i./L test levels. No sublethal effects were observed in the control and 5.6 mg a.i./L test levels. The study authors reported a 96-hour LC50 at 51.8 mg a.i./L.

- MRID 43946602: This study explored the acute toxicity of the desnitro/guanidine degradate to *Chironomus tentans*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the desnitro degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 0.1, 1.0, 10.0, and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *C. tentans* was used in the study at the 2nd instar stage. Mean measured concentrations reported in the study were 0.12, 0.87, 8.19, and 82.8 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors observed the following mortality: 15% in the controls, 15% at the 0.12 mg a.i./L level, 0% at the 0.87 and 8.19 mg a.i./L levels and 15% at the 82.8 mg a.i./L level. Sublethal effects (mottled coloration and erratic behavior) were found at the 8.19 and 82.8 mg a.i./L test levels. No sublethal effects were observed in the control, 0.12 and 0.87 mg a.i./L test levels. The study authors reported a 96-hour LC50 at 17.0 mg a.i./L.

- MRID 43946603: This study explored the acute toxicity of the urea degradate to *Hyallela azteca*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the urea degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 6.25, 12.5, 25, 50, and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *H. azteca* was used in the study and

individuals were 7 to 21 days old at test initiation. Mean measured concentrations reported in the study were 5.81, 11.80, 23.46, 46.80, and 94.83 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors observed very little mortality where one test organism died at 72 hours in the 94.83 mg/L level and 2 were missing (assumed dead) in control replicate A after 96 hours. No sublethal effects were found at any test concentration. The study authors reported a 96-hour LC50 at >94.83 mg a.i./L.

- MRID 43946604: This study explored the acute toxicity of the urea degradate to *Chironomus tentans*. The study employed a 96 hour static design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the urea degradate were made using a combination of both radio labeled and non-radio labeled test substance. Nominal concentrations for the definitive test included 0.1, 1.0, 10.0, and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *C. tentans* was used in the study and individuals were from 12 to 14 days old. Mean measured concentrations reported in the study were 0.10, 1.00, 10.04, and 99.80 mg a.i./L. No undissolved test substance was observed in any test chamber. The study authors reported very little mortality where one test organism died at 96 hours in the control and 100 mg a.i./L test levels. No sublethal effects were found at any test concentration. The study authors reported a 96-hour LC50 at >99.80 mg a.i./L.

- MRID 44558901: This limit test study explored the acute toxicity of the 6-chloronicotinic degradate to *Chironomus tentans*. The study employed a 96 hour static renewal design and the primary endpoint was mortality, but sublethal and behavioral effects were also observed. Concentrations of the 6-chloronicotinic acid degradate were made using non-radio labeled test substance. Nominal concentrations for the test included a control and 100 mg/L, and no solvent was used in the preparation of the test material. The control solution was made of dilution water only. *C. tentans* was used in the study and individuals were aged at 12 days post egg deposition at initiation. The study authors reported that the test material was stable in dilution water for 48 hours based on a separate stability analysis, but the authors did not confirm test levels in the study. No undissolved test substance was observed in any test chamber. The study authors very little mortality where one test organism died at 72 hours in the control. One organism exhibited sublethal effects of mottled coloration and abnormal position on top of the sand substrate at 48 hours. The study authors reported a 96-hour LC50 at >1 mg a.i./L.

It is also important to note that data submitted to EFSA[10] confirms the conclusions from the preliminary analysis above that the degradates are substantially less toxic to aquatic invertebrates than the parent compound. The studies explored the acute toxicity of imidacloprid 5-hydroxy (24 hour static) and nitroso (24 hour static) degradates, as well as the chronic toxicity of the desnitro (28 day chronic), urea (28 day chronic), AMCP (28 day chronic), and desnitro olefin (28 day chronic) degradates, to *Chironomus riparius* (**Table 7**). The European data suggest that the 5-hydroxy and nitroso degradates are both nearly an order of magnitude less toxic than the parent

[10] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005.

compound on an acute exposure basis to *Chironomus riparius*, which is a very sensitive aquatic invertebrate to imidacloprid exposure. The rest of the degradates, however, are several orders of magnitude less toxic than the parent compound, as seen on a chronic exposure basis. One area of uncertainty related to these degradates is long-term toxicity of the 6-chloronicotinic acid to benthic invertebrates. Parent imidacloprid is expected to persist at low levels in the sediment for extended periods of time. The identified degradates in the aquatic-sediment system are the desnitro, urea, desnitro-olefin, and 6-chloronicotinic acid degradates. Chronic toxicity information on the first three degradates shows that these degradates are much less toxic than the parent compound. Acute toxicity information indicate that the 6-chloronicotinic acid is less toxic than the parent compound. However, there are no currently available chronic toxicity studies with 6-chloronicotinic acid, which is the terminal degradate of imidacloprid and is likely to lead to chronic exposure for benthic invertebrates. Nonetheless, given the comparative acute toxicity information and lower toxicity relative to the parent compound, it is likely that 6-chloronicotinic acid would also be much less toxic on a chronic basis as well.

Table 7. Toxicity values from acute and chronic studies reported by EFSA but not to the Agency. These studies have not been formally reviewed by the Agency.

Species	Test substance	Test system – duration	Parameter	NOEC (mg/L)	EC_{50}/LC_{50} (mg/L)	Type of Conc.
G. pulex	Parent	Static – 28 d	Swimming behavior	0.064		Nominal initial
Chironomus riparius	Parent	Static – 28 d	Emergence	0.00225[1]	0.00311	Nominal initial
Chironomus riparius	TEP: Confidor SL 200	Static – 28 d	Development, emergence	0.0027[1]	0.0036	Nominal initial
Chironomus riparius	Urea	Static – 28 d	Development, emergence	73.6[1]	248.7	Nominal initial
Chironomus riparius	AMCP	Static – 28 d	Development, emergence	> 105[1]	>105	Nominal initial
Chironomus riparius	Desnitro – olefin	Static – 28 d	Development, emergence	12.4[1,2]	21.3[3]	Nominal initial
Chironomus riparius	Desnitro	Static – 28 d	Development, emergence	33.61[1,2]	45.99[3]	Nominal initial
Chironomus riparius	5-hydroxy	Static – 24 h	Mortality		0.668	Nominal initial
Chironomus riparius	Nitroso	Static – 24 h	Mortality		0.283	Nominal initial

[1] EC_{15}
[2] Development rates of males
[3] Emergence ratio of pooled sexes

The toxicity of these degradates to fish is an uncertainty though because no toxicity data on the degradates have been submitted related to fish. EFED re-evaluated the degradates for this assessment using quantitative structure activity relationships provided by the EcoSAR module in EPISUITE v4.1[11] to reveal potential toxicity levels of each of these degradates to fish and those that are most relevant to the aquatic exposure assessment are listed in bold (**Table 8**). Considering the stability of the parent compound and the tidal nature of the aquatic environment,

[11] http://www.epa.gov/opptintr/exposure/pubs/episuite.htm

aquatic organisms are not likely to experience an acute peak of exposure to any of the degradates listed in **Table 8**. Instead, exposure would more likely be repeated exposures to low levels of degradates. Consequently, the chronic values estimated by EcoSAR would be most relevant. The most sensitive chronic endpoint from all of these degradates to fish was estimated to be 523 ppb from the nitrosamine degradate[12] due to the hydrazine structure; however, the nitrosamine degradate is a plant and animal metabolite and is therefore not expected to be relevant for exposure in the aquatic environment. The desnitro-olefin degradate showed the lowest estimated toxicity to fish (682 ppb), and the other degradates showed chronic endpoints higher than this degradate. Note that the chronic NOAEC and LOAEC for the parent imidacloprid from a study with rainbow trout are 1.2 and 2.5 ppm, respectively. These two values are nearly two orders of magnitude different than the 111.317 ppm value estimated by EPISUITE for parent imidacloprid, which suggests that EPISUITE is poorly estimating the potential toxicity of imidacloprid.

Table 8. Summary of EcoSAR results showing estimated toxicity values relative to fish chronic toxicity.

Degradate	Functional Group[a]	Chronic Endpt[b]
Imidacloprid parent	Aliphatic amine	111.317
Imidacloprid 5-hydroxy	Aliphatic amine	874.287
Nitrosamine (nitroso)	Hydrazine	0.523
Desnitro	**Aliphatic amine**	**4.121**
Urea	**Amide**	**1.921**
AMCP	Aliphatic Amine	4.668
Desnitro olefin	**Vinyl/allyl amine**	**0.682**
6-chloronicotinic acid	**Halopyridine acid**	**12.122**

[a] The functional group that yields the most sensitive endpoint in fish
[b] 32-day Chronic Value in ppm

In summary, the parent compound shows high levels of toxicity to free-swimming and benthic invertebrates, but relatively low toxicity to fish. EFED concludes that the degradates are not a concern to aquatic invertebrates, but rather the parent compound is the toxicologically relevant compound. In the case of fish, the toxicity of the degradates is uncertain due to the poor performance of the EcoSAR module of EPISUITE in estimating toxicity. Further consideration of the toxicity of the degradates to fish is provided in the risk characterization section of this assessment.

Terrestrial Hazard Summary

Imidacloprid appears to be highly toxic to avian species on an acute dose based level to the Japanese Quail (LD_{50} = 31 mg a.i./kg bwt) and slightly to practically non-toxic to birds on a

[12] See Appendix 3 for chemical structure. Target site potency and selectivity of neonicotinoid insecticides may be "retained when the usual neonicotinoid N-nitroimine (=NNO(2)) electronegative tip is replaced with N-nitrosoimine (=NNO) or N-(trifluoroacetyl)imine (=NCOCF(3))". See: Tomizawa M, Zhang N, Durkin KA, Olmstead MM, Casida JE. 2003. The neonicotinoid electronegative pharmacophore plays the crucial role in the high affinity and selectivity for the Drosophila nicotinic receptor: an anomaly for the nicotinoid cation--pi interaction model. Biochemistry 42(25):7819-27.

subacute level (Bobwhite quail LC_{50} = 1,536 ppm; Mallard duck LC_{50} > 4,797 ppm). However, exposure to the granular product (2.5G) on a dose basis could result in high toxicity to small birds (house sparrow LD_{50} = 41 mg/kg) and confirms the results of the study with Japanese quail that imidacloprid is highly toxic to some avian species. It also confirms that Bobwhite quail and especially the Mallard duck are relatively less sensitive to imidacloprid exposure. Consequently there is uncertainty related to the dietary toxicity of imidacloprid due to relatively insensitive species being tested in these studies. In terms of chronic toxicity, data show that imidacloprid exposure can result in egg shell thinning and a decrease in adult weight (NOAEC/LOAEC = 36/>61 ppm).

Mammalian toxicity data suggest that this compound is moderately toxic on an acute basis (LD_{50} = 424 mg/kg) to small mammals. Reproductive effects were noted at 250 ppm.

Terrestrial invertebrates are very sensitive to imidacloprid. Acute toxicity data on honeybees show that imidacloprid is very highly toxic to non-target insects (LD_{50} = 0.0039 for acute oral and LD_{50} = 0.078 ug/bee for acute contact). There are also data on the toxicity of residues on foliage for imidacloprid which shows an RT_{25} of 8 hours for the maximum application rate of 0.5 lb a.i./A (MRID 42632901). In addition, a preliminary review of the open literature suggests in general that imidacloprid has a strong potential to elicit sublethal effects. However, uncertainty remains as to how these sublethal effects translate into effects impacting survival, growth, or reproduction.

Risk Characterization

Risk to Aquatic Organisms

The risk from upper bound exposure scenarios are presented in **Tables 9**, **10**, and **11**. The scenarios reflect the two formulations that are proposed for use on oyster beds in Willapa Bay and Grays Harbor. In these two scenarios, some of the EEC's are presented based on theoretical concentrations, while others are based on measured concentrations. The differences between these two concentrations are important to keep in mind as the EEC's based on measured concentrations reflect actual residues measured *in situ*, but as noted earlier there are uncertainties associated with these measured concentrations due to limited submissions of sampling data.

Acute Risk

For acute exposure, the parent compound is the stressor of concern. Several lines of thought lead to this conclusion. First, the persistence of imidacloprid in aquatic systems as indicated by the equivalency in concentrations between peak exposure to the parent compound and the total residues shown in **Tables 2 – 5** reveals that the parent compound makes up the entire total residues for the first 24 hours of exposure. Furthermore, the flushing of the system due to the tidal nature of the mudflat habitat combined with the solubility of imidacloprid suggests that peak concentrations of parent imidacloprid may be removed from the surface water with the tide thereby leaving little residue to degrade in overlying water. In fact, **Tables 4** and **5** show the precipitous decline in residues after only 24 hours, implying that the applied imidacloprid rapidly dissipates from the system and high exposures persist for a very short amount of time.

Consequently, those organisms present on the mudflat at the time of application would experience high levels of exposure in overlying water, but organisms that migrate onto the mudflats after 24 hours would experience substantially lower levels of exposure.

Table 9. Range in exposure and acute risk to aquatic animals and risk to aquatic plants due to parent and total residues of imidacloprid in overlying water on the site of application at 0-0.1 days after treatment. RQ values in bold exceed the Agency level of concern.

Scenario/App. Rate	Depth of Water	Aquatic Animals [a]				Aquatic Plants [b]
		Type of EEC (ppb)	EEC (ppb)	Estuarine/ Marine Fish	Estuarine/ Marine Invertebrates	Non-Vascular (non-listed/ listed)
Uses						
Flowable: 0.5 lb a.i./A	3 cm[c]	Min	244	0.001	**7**	0.02
		Max	872	0.005	**24**	0.09
	10 cm[c]	Min	180	0.001	**5**	0.02
		Max	320	0.002	**9**	0.03
	<10 cm[d]	Max	1400	0.009	**38**	01

[a] Toxicity values are based on studies with mysid shrimp (*Mysidopsis bahia*) for estuarine/marine invertebrates (EC_{50} = 37 µg a.i./L), and sheepshead minnow (*Cyprinodon variegatus*) for estuarine/marine fish (LC_{50} = 163,000 µg a.i./L).
[b] Toxicity values are based on studies with green algae (*Scenedesmus subspicatus*) for non-vascular plants (EC_{50} > 10,000 µg a.i./L; NOAEC = 10,000 µg a.i./L). No other data are available for aquatic vascular and non-vascular plants.
[c] Theoretical concentrations based upon estimated concentrations in the water column.
[d] Maximum measured concentration from monitoring data on-bed at the site of application.

Table 10. Most conservative exposure scenarios for acute risk to aquatic animals and risk to aquatic plants due to estimated levels of parent imidacloprid in shallow tidal water with different types of sediment and mixing depth. RQ values in bold exceed the Agency level of concern.

Scenario/App. Rate	Location	Type of Sediment	Sediment Mixing Depth	Reference Water Depth	Peak EEC (ppb)	Aquatic Animals [a]		Aquatic Plants [b]
						Estuarine/ Marine Fish	Estuarine/ Marine Invertebrates	Non-Vascular (non-listed/ listed)
Uses								
Flowable: 0.5 lb a.i./A	Shallow tidal water	Fine	3	3	600	0.004	**16**	0.06
		Fine	10	3	245	0.002	**7**	0.02
		Sandy	3	3	872	0.005	**24**	0.09

[a] Toxicity values are based on studies with mysid shrimp (*Mysidopsis bahia*) for estuarine/marine invertebrates (EC_{50} = 37 µg a.i./L), and sheepshead minnow (*Cyprinodon variegatus*) for estuarine/marine fish (LC_{50} = 163,000 µg a.i./L).
[b] Toxicity values are based on studies with green algae (*Scenedesmus subspicatus*) for non-vascular plants (EC_{50} > 10,000 µg a.i./L; NOAEC = 10,000 µg a.i./L). No other data have been reviewed for aquatic vascular and non-vascular plants.

As shown in **Table 9** and **Table 10**, the peak concentrations based on both theoretical and measured concentrations lead to risk below the LOC for fish. In fact, acute exposure values do not exceed the LOC for either listed or non-listed estuarine/marine fish at on-site locations and

consequently would not exceed the LOC at off-site locations where concentrations are likely to be substantially lower. Consequently, EFED does not anticipate that the use of either formulated product will negatively affect fish based on direct toxicity at the site of application in Willapa Bay and Grays Harbor where water concentrations are expected to be the greatest.

Similar to fish, EFED also does not anticipate that risk to aquatic plants will exceed the LOC either at on-site or off-site locations based on the RQ's presented in **Tables 9** and **10**. Risk to plants represents an uncertainty however, in that the only available study that has been reviewed on aquatic plants for imidacloprid relates to aquatic non-vascular plants. Therefore, the risk picture for aquatic vascular plants due to the proposed uses remains uncertain even though the current data indicate minimal risk. Additional data on the toxicity of imidacloprid to *Lemna gibba* (MRID 48648601) has been submitted but is currently in review.

In contrast to the other taxa, acute risk to invertebrates other than mollusks in Willapa Bay and Grays Harbor immediately after applications exceeds the LOC for both listed and non-listed species. Mollusks appear to be considerably less sensitive to imidacloprid than other invertebrate taxa. The extent of the risk is also important to consider. For on-site applications, the risk is well above the LOC, and EFED anticipates that non-target invertebrates, including free-swimming as well as benthic for which mysid shrimp serve as a surrogate, at the site of application will be at substantial risk for direct toxicity from imidacloprid where RQ's range from 5 up to 38. Benthic invertebrates are also considered to be at acute risk given that maximum concentrations used for RQ estimation in **Tables 9** and **10** for overlying water are similar to maximum pore-water concentrations in **Tables 2** and **3**, and the same toxicity endpoint for mysid shrimp would be used.

Considering off-site acute risk, EFED assessed the distance of 30ft off-site from the application area and in the direction of tidal outflow. Concentrations in pore-water are close to the detection limit, and therefore overlying water concentrations are expected to be negligible. However, when comparing the estimated pore-water EEC's to the mysid shrimp toxicity data, the off-site RQ for the flowable formulation is 0.05, and it is 0.02 for the granular formulation. The flowable formulation reaches the listed species LOC of 0.05, but these peak concentrations are not expected to remain for very long. These risk estimates off-site are based on actual measured concentrations from data provided by the Oyster Growers Association of Willapa Bay and Grays Harbor. Thus EFED concludes that risk to federally listed benthic invertebrates would remain above the LOC even to the extent of 30ft off-site, but not for non-listed free-swimming or benthic invertebrates. However, it should be noted that there are no benthic invertebrates that are currently listed as threatened or endangered in Willapa Bay and Grays Harbor. EFED also notes that there is uncertainty in the exposure estimates for off-site locations given the need for additional monitoring data.

Chronic Risk

In terms of chronic risk, **Table 11** reveals a trend similar to that for acute risk. The chronic EEC's do not exceed the LOC for either listed or non-listed estuarine/marine fish. The lack of exceedances relates to both parent imidacloprid and when total residues are taken into consideration. Regarding potential risk to fish from exposure to the degradates, **Table 8** shows

that most of the estimated chronic endpoints for the degradates are well above the estimated exposure concentrations. Yet these comparisons contain uncertainty. To explore this uncertainty a bit further, the conservative assumption can be made that all of the total residues at the final time point are made up of the degradate of concern. For example, the maximum 35-day on-site EEC for the parent compound in overlying water is estimated to be 21.53 ppb (

Table 6). As **Table 4** shows, the ratio of the parent to the total residues in pore water at 28 days after application indicates that the parent comprises 32% of the total residues. Consequently, in the case of desnitro olefin, 68% of the total residues could be conservatively assumed to be the desnitro olefin, which is estimated to be the most toxic of the relevant degradates, leading to a concentration of 45.75 ppb. In this case, the desnitro olefin degradate would have to be nearly two orders of magnitude more toxic than the estimated endpoint.

Considering that EPISUITE is underestimating toxicity of the parent compound by approximately two orders of magnitude, it is possible that the estimated toxicity endpoint for the desnitro olefin is also underestimated by two orders of magnitude leading to a chronic endpoint of approximately 6.82ppb. The desnitro olefin may therefore be of toxicological concern related to chronic exposure. In addition, the chronic toxicity endpoints for the urea degradate would be 19.21ppb and the desnitro (guanidine) would be 41.21ppb, so both of these degradates would also be of concern. The uncertainty therefore relates to the concentrations of the degradates in the tidal estuary and the obvious underestimation of toxicity by EPISUITE. From an exposure basis, fish would have to return to the same mudflats to receive repeated pulses of exposure. In addition, all of the total residues would have to be in the form of the relevant degradates identified above. These are conservative assumptions. In addition, to date, EFED is not aware of information on the formation rates specifically of the desnitro olefin in estuarine-marine systems so it is unclear to what extent this degradate may form. From the *in-situ* monitoring data available, it appears that overlying water concentrations on bed of the parent compound are below detection limits after one to three days post application, which is different than the modeling results and indicates that actual overlying water concentrations may be negligible. Yet pore water data using the ELISA method reveal that the desnitro, olefin, and urea degradates are forming. In summary, EFED concludes that exposure of fish to the degradates and the consequent risk may be minimal; however, there is uncertainty as to the actual concentrations of the degradates in the overlying water due to only partial submissions of monitoring data and lack of toxicity testing of these degradates on fish. In light of these uncertainties, EFED is not able to make any definitive risk conclusions regarding the potential for chronic exposure to the degradates for fish at on-site locations. Based on comparisons between on-site and off-site pore water residue levels, EFED anticipates that off-site concentrations of the degradates in overlying water will be negligible, therefore the primary uncertainty for chronic exposure to fish is relevant to on-site areas that have received a direct application.

Unlike fish, risk exceeds the chronic LOC for free-swimming and benthic invertebrates on the site of application. When considering off-site risk, the RQ's slightly exceed the LOC for benthic invertebrates. There is uncertainty in this comparison and these RQ's related to sediment toxicity, however. The sediment toxicity value is based on the mysid shrimp, and it is unclear how well the mysid toxicity relates to benthic invertebrate toxicity. No acceptable data have

been submitted that address benthic invertebrates in estuarine/marine systems. Chronic concentrations in overlying water are expected to be negligible off-site as the pore-water concentrations are themselves barely above the detection limit, though there is uncertainty due to an incomplete evaluation of residue levels in overlying water because of only partial submissions of data.

It is important to consider that the EEC's used to calculate the RQ's for the benthic invertebrates are based on total residues. Given the data currently submitted to Europe and the Agency regarding the degradates, noting the uncertainty of not having reviewed this data and the lack of chronic toxicity data on sediment invertebrates, EFED does not anticipate the degradates to be of significant concern to benthic invertebrates and therefore the concentrations of parent imidacloprid are likely the residues of concern. **Table 4** reveals instantaneous water concentrations and shows that at 28 days, the parent makes up 32% of the total residues measured. If this percentage is applied to the off-site RQ's in **Table 11**, the RQ for the flowable formulation just reaches the LOC of 1, but the RQ for the granular formulation falls below the LOC. Another important consideration is that the residues are only detected in off-site pore-water up to 14 days post application. By day 28 residues are not detectable, and consequently the exposure would not persist to 28 days. Consequently, EFED anticipates potential chronic risk for benthic invertebrates up to 30ft off-site from the flowable formulation, but not for the granular formulation, and notes that concentrations appear to drop below detection limits by 28 days post application.

Table 11. Measured pore water concentrations and chronic risk to aquatic animals and risk due to parent and total residues of imidacloprid on-site. Risk Quotient values in bold exceed the Agency level of concern.

Scenario/App. Rate	Location	Residue of Concern	Aquatic Animal RQs [a]				
			21 day/ 35 day overlying water EEC (ppb)[b]	21 day pore water EEC (ppb)[c]	Estuarine/ Marine Fish	Estuarine/ Marine Free-swimming Invertebrates	Estuarine/ Marine Benthic Invertebrates
Uses							
Flowable: 0.5 lb a.i./A	On-site	Parent	31.66/ 21.53	34.3	0.02	**53**	**57**
		Total Residues	N/C[d]	107.1	N/C	N/C	**179**
	Off-site	Total Residues	N/C	1.6	N/C	N/C	**3**
Granular: 0.5 lb a.i./A	On-site	Parent	N/C	9.9	N/C	N/C	**17**
		Total Residues	N/C	30.8	N/C	N/C	**51**
	Off-site	Total Residues	N/C	0.5	N/C	N/C	**1**

[a] Chronic toxicity values are based on studies with a free-swimming saltwater invertebrate mysid shrimp (*Mysidopsis bahia*) (NOAEC = 0.6 µg a.i./L) and rainbow trout (*Oncorhynchus mykiss*) for freshwater fish (NOAEC = 1200 µg a.i./L). For benthic invertebrates, the chronic toxicity value is also based on mysid shrimp due to a lack of data on benthic saltwater invertebrate species.
[b] EEC's in overlying water for use in calculation of fish and free-swimming invertebrate RQ's. Overlying water concentrations are based on the maximum overlying water concentration from the most conservative scenario with the flowable formulation on sandy sediments with

minimal overlying water at the time of application (Table 6).
[c] EEC's in pore water for use in calculation of benthic invertebrate RQ's.
[d] N/C = the EEC's were not calculated, but rather only the maximum 14 day.

For free-swimming invertebrates, chronic risk as identified above has some uncertainty. First, chronic exposure assumes that the same organisms migrate to the same location following multiple tide cycles. Second, the overlying water concentrations from the in-situ monitoring data show that residues are expected to rapidly dissipate and are not detectable after 24 hours post application. Third, the degradates appear to be much less toxic to aquatic invertebrates relative to the parent compound. So while low levels of residues persist in pore-water over time, the limited monitoring data suggest that these residues may not remain in overlying water. EFED raises the concern, however, that additional data have yet to be submitted that may shed more light on the concentrations in overlying water. At present, EFED therefore concludes that based upon modeling estimates, the potential chronic risk exceeds the LOC for free-swimming invertebrates on the site of application.

A number of reports have been informally submitted to the Agency that assess the biotic communities in order to shed light on the risk conclusions from this screening level assessment. These reports include data on the effects of imidacloprid to invertebrate and fish populations living on the oyster beds following applications of imidacloprid. However, the data were not formally submitted for review and are partial and/or incomplete. The studies include:

> "Appendix A: Field trials of imidacloprid against burrowing shrimp, 2011".
> [This is a preliminary report on the results of the 2011 residue and effects monitoring; a full citation was not available and the data provided were preliminary and incomplete. Additional review of the 2011 data may be warranted when a complete report is formally submitted to the Agency. This report is expected to provide further information on the concentrations of imidacloprid in the water column, pore-water, and in sediments arising from applications to oyster beds. The report is also slated to provide further validation of the precision and accuracy of an ELISA analytical technique compared to the standard HPLC technique.]
>
> Booth, S.R., K. Rassmussen, and A. Suhrbier. 2011. Impact of imidacloprid on epi-benthic and benthic invertebrates: 2011 studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp: Preliminary results from one of two study sites and three of five sample dates. This is a preliminary report on the results of the 2011 effects monitoring; a full citation was not available and the data provided were preliminary and incomplete. Additional review of the 2011 data may be warranted when a complete report is formally submitted to the Agency.

These data include evaluations of the abundance, diversity, and richness of three taxa including polychaetes, mollusks, and crustaceans on the site of application at three time points up to 28 days post application. These preliminary data from Booth et al., 2011, do not show significant differences in the comparisons between the treated plots and the control plots. However, when the data are looked at in terms of time trends and what occurs on the plots over time to 28 days post-application, the overall trends in abundance for polychaetes and crustaceans decrease, but not for the mollusks. A preliminary review suggests that diversity and species richness do not appear to be affected, but rather the main impact is to abundance. For example, at the Bay Center plot following applications of granular imidacloprid at 0.5lb/A on July 15, the overall abundances of polychaetes, mollusks, and crustaceans on the treated plot at day 28 post

application (final measurement point) were 36%, 432%, and 50%, respectively, of the day 0 levels. As a comparison, day 28 overall abundances of these taxa in the reference plots were 68%, 114%, and 141%, respectively, of the day 0 levels. These data do not identify recovery in abundance but rather simply capture time points on a decreasing trend. However, this data is from only one of two study areas, and the study report has not been formally submitted. Furthermore, no data were presented on impacts to these three taxa off-site. So while chronic effects to these two taxa appear possible for both formulations at least 28 days post application on site, EFED cannot draw any robust conclusions from the submitted information. Nonetheless, the preliminary data confirm the concerns highlighted in this risk assessment that acute and chronic exposure pose a concern for invertebrate communities on the site of application. The data also highlight the concern that increasing acreage subject to application from potential increases in ghost and mud shrimp recruitment rates can lead to increases in the spatial extent of long-term impacts on invertebrate abundances, including polychaete and crustacean taxa.

A final point to note is that the substrate to which imidacloprid is applied appears to make a difference. Sandy substrates contribute to higher concentrations of imidacloprid in overlying water according to modeled estimates. Therefore, the risk concerns for overlying water highlighted above are most pressing for sites with sandy substrates. Additional monitoring data provided by the 2011 and 2012 EUPs are important as they may potentially address this uncertainty.

Summary of Risks to Aquatic Organisms

In summary, the primary organisms of concern due to direct toxicity from both acute and chronic exposure are the benthic and free-swimming estuarine/marine invertebrates. The uses of the flowable and granular formulations present risks that exceed all LOC's at onsite locations on an acute basis for free-swimming and benthic invertebrates that inhabit the sediment. In terms of chronic exposure, the RQ's exceed the LOC at onsite locations for both flowable and granular formulations for benthic invertebrates. Free-swimming invertebrates are also at risk due to chronic exposure on the site of application. Off-site risk is only present for listed benthic invertebrates on an acute and chronic basis due to the flowable formulation. In addition, it appears that sandy substrates in the bays are more prone to higher exposures, at least in overlying water, than finer texture substrates. The submitted monitoring report, however, indicates that the overlying water contains very little imidacloprid at 21 days post application and would likely not impact free-swimming invertebrates in the overlying water following chronic exposure. These data have not been formally submitted and have not been reviewed by EFED. In contrast,, according to modeling estimates, low residues in overlying water, as well as pore water, can persist weeks after applications. Therefore, there is uncertainty in the comparison of the overlying water and pore water concentrations over time related to aquatic invertebrate toxicity. Aquatic invertebrate taxa represent the base of the food chain, and impacts on these taxa will likely cascade up the food chain, resulting in a reduction in prey and modification of PCE's related to endangered species due to fewer prey, as highlighted in the conceptual diagram in **Figure 1**. Additionally, individual effects on these organisms, including crab species, can also be expected. Recruitment of other individuals to on-site locations following removal of the shrimp may be a significant pathway of recovery for the impacted taxa. However, the submitted biotic monitoring data indicate potential decreases in abundance for crustaceans and polychaetes

at least 28 days post application without evident recovery, although these results are uncertain as well because the data are partial or incomplete and have not been formally submitted for review. Nonetheless, the submitted biotic monitoring data support the aquatic invertebrate risk conclusions contained in this assessment.

While EFED recognizes that acute mortality in the immediate application site may be very high for aquatic animals trapped in tide pools and/or living in benthic sediments, the potential for off-site effects and overall impact to Willapa Bay as a whole appears limited. This is based on estimates that roughly 10% of the total acres (79,000 total acres) of the bay are under shellfish production during any given year, the label allows only one application per year, and that during a complete tidal cycle (low tide to high tide), as much as 25.4 million ft_3 of water (up to 45% of the bay's total volume) may be exchanged. Thus, the opportunity for dilution alone is significant. Although this discussion has focused primarily on Willapa Bay, it is believed that the same potential for dissipation exists for Grays Harbor where a similar percentage of the total acreage may be treated. However, EFED also notes that the potential acreage to which imidacloprid will be applied may increase if recruitment rates of ghost and mud shrimp increase. Consequently, a number of factors suggest that any increases in the acreage treated may be accompanied by increases in the spatial extent of consequent long-term impacts to the aquatic invertebrate assemblage and potential indirect effects to taxa that depend on these invertebrate species. These factors include the persistence of imidacloprid in sediment pore water for weeks after the initial application, the sensitivity of certain marine taxa to imidacloprid, the results from the risk assessment showing acute and chronic LOC exceedances for estuarine free-swimming and benthic invertebrates, and the preliminary indication that chronic effects are possible that reduce abundance of polychaete and crustacean taxa on the site of application at least up to 28 days post application without apparent recovery. It is also important to note that these impacts are primarily on the site of application with little concern off-site. Uncertainty remains regarding the risk picture off-site due to yearly applications of imidacloprid to the same oyster beds, potential increases in the acreage to which imidacloprid will be applied, and the persistence of imidacloprid residues in the sediment pore water where the concern is that residues may remain available or increase off-site over time. Consequently there is uncertainty in the spatial extent of the residues and potential impacts off-site.

Risk to Terrestrial Organisms

Plants

Imidacloprid is to be applied as a granule or spray to intertidal oyster beds. Consequently, EFED does not anticipate movement off-site via spray drift of the granule or flowable product to be a significant pathway of exposure to terrestrial plants. Therefore, risk concerns to terrestrial plants are considered negligible for the current assessment.

Birds and Mammals

A pathway of exposure from both flowable and granular formulations to both birds and mammals is through contact with contaminated sediment or vegetation following application. At the present time, the Agency does not have a method to quantify these levels of exposure, and data are limited to quantify the contribution of such exposures to the toxic burden an organism

experiences. The Agency is actively working on a screening method to quantify exposure from direct impingement of applied foliar as well as bare ground sprays, granular applications, and from incidental contact with dislodgeable foliar pesticide residues from treated or drift-impacted vegetation. Given the application methods available for imidacloprid, this route of exposure for terrestrial wildlife is possible, but no quantification of exposure concentrations and attendant risks is possible until the completion of initial screening models.

Another way that birds and mammals can be exposed to imidacloprid from the granular formulation is that birds and mammals may feed directly on the granules that may be scattered on the surface of the mudflats. The granules, formulated as Protector 0.5G, are to be spread with a conventional pesticide applicator, helicopter, or ground based vehicle. There is no restriction as to how this granule should be applied, and so applications to low tide mudflats may be made. These applications would then result in the granules remaining on the surface until either dissolution or movement following inundation from the next tide. Consequently, birds or mammals that feed in these tidal mudflats may mistake the granules for seeds and directly consume the granules. In order to evaluate the potential hazard from this method of exposure, TREX was used to ascertain the LD_{50}'s per square foot. **Table 12** shows the results of this analysis.

Table 12. The number of LD50/ft2 present following an application of Protector 0.5G at 0.5lb a.i./A. The avian values are based on the acute oral toxicity to Japanese Quail, and the mammalian values are based on acute toxicity to the rat.

Broadcast applications		
Granular		
Intermediate Calculations		
mg a.i./ft2:	**5.21**	
LD50 ft-2		
	wgt class (grams)	
Avian	**20**	**11.14**
	100	**1.75**
	1000	**0.12**
Mammal	**15**	**0.37**
	35	**0.20**
	1000	**0.02**

As **Table 12** shows, small mammals and, in particular, small birds would be of primary concern for exposure to the granules. However, there are important considerations when approaching these LD_{50}/ft^2 values. First, food items within an animal's diet is important to determining the potential risk of the granular application on tidal mudflats. Smaller birds that feed on tidal mudflats, such as the shore birds, are unlikely to view granules as food items given their reliance on invertebrate or small fish as prey[13]. Larger birds, such as waterfowl, would be more likely to

[13] ftp://ftp-fc.sc.egov.usda.gov/WHMI/WEB/pdf/SHOREbirds1.pdf

consume the granules mistakenly as seeds as their diets include more vegetative food items. As **Table 12** shows though, there are substantially fewer LD_{50}'s/ft^2 for large birds.

In addition, possible avoidance behavior by birds is an important consideration given the potential for consumption of the granules. Data submitted to the EPA suggest that some birds show avoidance of imidacloprid and that imidacloprid may lead to sublethal effects that reduce feeding on contaminated food sources. A previous review (D205523; 08/22/94) summarized the data on avoidance behavior and found that some birds immediately avoided the contaminated food (house sparrow) or showed immediate consumption of the food followed by a reduction in contaminated food consumption (turtledoves). In one study submitted to the European Union[14] but not to the U.S. EPA, the avoidance of contaminated material was found in a dietary study with the Japanese quail, which is also the most sensitive species based on acute oral toxicity data. In all cases, birds appear to develop avoidance of imidacloprid contaminated food items. A similar avoidance would likely be exhibited for granules that may be used as a food source by birds in the larger weight class, which is also the less sensitive of the different size classes. Considering the use pattern and the short duration during which the granules would be available prior to inundation as well as the limited acreage to which imidacloprid would be applied as a granule, acute exposure to birds through direct consumption of the granules is of low concern and chronic exposure is negligible based on the tidal nature of the system and the dilution of imidacloprid. Consequently, EFED expects negligible risk due to consumption of granules by birds.

In a similar manner, **Table 12** shows that there is relatively less concern for large mammals than for small mammals. However, small mammals are unlikely to forage in the mudflats where oysters would be grown due to the potential for exposure and then predation. However, larger mammals may move to the mudflats to feed and forage. According to **Table 12**, there are only 0.02 LD_{50}/ft^2, which indicates that there is relatively little toxicity to large mammals per square foot given the assumption that a mammal consume the granules. Therefore, similar to birds, direct consumption of granules is of low concern as a route of exposure to mammals on tidal mudflats.

A final pathway of exposure to birds and mammals is through contamination of food items. Food items may include plant material as applications may be made where eelgrass is present. In addition, food items would also include invertebrates that are directly sprayed during low tide and fish and invertebrates that are contaminated through uptake following exposure in the water column or through contact with sediments in between low tides. For fish and invertebrates that are exposed to imidacloprid in the water column or through contact with the sediment, body burden concentrations are expected to be negligible with minimal accumulation within the food chain due to the low K_{ow} of imidacloprid. For chemicals with Log $K_{ow} < 4$, exposure from food becomes insignificant because uptake and depuration across the gills controls the residue in the organism. Imidacloprid is highly hydrophilic with a log Kow of 0.57 and therefore would not accumulate appreciably in the stored fats of invertebrates or fish. Consequently, these prey items would likely have little contamination for birds and mammals feeding on them. **Table 13**

[14] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005. Table 2.6-6

presents the results of the exposure modeling and consequent risk conclusions. As expected, the acute risk is all well below the various levels of concern.

Chronic risk via this pathway of exposure is an uncertainty due to the tidal nature of the ecosystem. As the data to date show, most of the residues in the water column and sediment pore water are removed from the system following the first tidal inundation. Therefore, low concentrations of persistent residues in the sediment combined with extremely limited potential for bioaccumulation leads to EFED's conclusion that chronic risk to birds and mammals is negligible from feeding on organisms exposed to concentrations of imidacloprid in the water column and sediments. However, there is uncertainty as not all of the data for imidacloprid applications to oyster beds have been submitted yet.

EFED also used KABAM to evaluate chronic exposure, and as expected **Table 13** shows little concern for birds and mammals that are chronically exposed to imidacloprid from eating aquatic food items contaminated by bioaccumulation.

Table 13. Calculation of Risk Quotient values for mammals and birds consuming fish contaminated by Imidacloprid using KABAM. Across the range of potential mammal and bird body weights, none of the RQ's exceed any level of concern. Modeling with KABAM used the default input values, which represents a conservative scenario of exposure and potential accumulation within the food chain. The imidacloprid input parameters for water column EEC and pore water EEC were 38.9 and 97 ppb, respectively, which were residue levels at one day after application based on a KABAM calculated 2 days to steady state.

Wildlife Species[a]	Acute RQ		Chronic RQ	
	Dose Based	Dietary Based	Dose Based	Dietary Based
Mammalian				
fog/water shrew	0.000	N/A	0.001	0.000
rice rat/star-nosed mole	0.000	N/A	0.001	0.000
small mink	0.000	N/A	0.001	0.000
large mink	0.000	N/A	0.001	0.000
small river otter	0.000	N/A	0.002	0.000
large river otter	0.000	N/A	0.002	0.000
Avian				
sandpipers	0.002	0.000	N/A	0.001
cranes	0.000	0.000	N/A	0.001
rails	0.001	0.000	N/A	0.001

herons	0.000	0.000	N/A	0.001
small osprey	0.000	0.000	N/A	0.001
white pelican	0.000	0.000	N/A	0.001
[a] Wildlife species used in the modeling are default species and reflect a range of body sizes and food consumption patterns to illustrate the lack of concern due to consumption of contaminated aquatic prey species.				

The use of the flowable formulation as a spray may also result in surface contamination of plants and invertebrates remaining on the mudflats during applications to exposed mudflats. Some birds may eat eelgrass as a component of their diet. In addition, birds and mammals are likely to consume invertebrates as they forage in the mudflats. Fish would not be a food source to consider in this scenario as any fish would have moved out of the tidal mudflat with the retreating tide. And considerations with fish are covered by the previous scenario that EFED evaluated using KABAM. As a conservative estimation of risk to birds and mammals feeding on these food sources, TREX was used with the tallgrass scenario (eelgrass may grow up to 1.2m in length[15]) to reflect consumption of plant material by birds and mammals, and the arthropod scenario reflected consumption of invertebrates that may be exposed to direct sprays of Protector 2F. The results are presented in **Table 14**. Again, due to the tidal nature of the system, chronic risk is expected to be minimal. Given the solubility and low K_{ow} of imidacloprid, the residues on any exposed invertebrates are likely to move into solution when the tide returns. Consequently, the chronic exposure via this pathway would be negligible following the first tidal inundation after the spray event and therefore not pose any chronic risk concerns.

Table 14. Acute RQ's based on the tallgrass and arthropod scenarios in TREX for birds and mammals consuming prey items contaminated by direct exposure to sprays during low tide.

Scenario	**Avian RQ's**			**Mammalian RQ's**		
	20g	**100g**	**1000g**	**15g**	**35g**	**1000g**
Tallgrass	**2.68**	**1.2**	**0.38**	0.06	0.05	0.03
Arthropod	**2.29**	**1.03**	**0.33**	0.05	0.04	0.02

As **Table 14** reveals, there are no mammalian acute risk concerns, but risk exceeds the acute level of concern for birds. The RQ exceeds the LOC for federally listed large birds such as waterfowl that feed on either eelgrass or aquatic invertebrates. In addition, both listed and non-listed medium and small birds, such as shorebirds, would also be of concern based on the exceedance of the listed and non-listed species LOC's. It is important to remember that these exceedances correspond to acute toxicity related to applications of Protector 2F made specifically at low tide to exposed mudflats with minimal or no standing water.

It is also important to note that there is uncertainty in these exposures in TREX. TREX estimates are based on the Kenaga nomogram using residue data on terrestrial plants and invertebrates. It is unknown how well these exposure values relate to applications made on tidal mudflats and the plants and invertebrates that occupy these habitats. Furthermore, the invertebrates on the tidal mudflats would likely burrow during periods of low tide to escape predation, and so they are

[15] http://plants.usda.gov/java/profile?symbol=ZOMA

unlikely to be exposed when there is no water covering the mudflat as a spray application is made. While unlikely, it is still possible that the invertebrates may be exposed to direct spray applications. Plants would be present, and so while consumption of invertebrates exposed to direct spray applications of Protector 2F is unlikely, consumption of contaminated plants is more likely and presents the primary concern related to this application. Consequently, there is little concern for mammals at all, and little concern for birds when Protector 2F is applied with standing water. However, use of Protector 2F during the peak of low tide when a mudflat is completely exposed poses a risk concern to listed and non-listed birds that consume invertebrates and most especially plant material.

Invertebrates

Terrestrial invertebrates are unlikely to be in the vicinity of the tidal mudflats during applications while water is present, therefore exposure, especially to bees, would be negligible. However, invertebrates other than bees may move into the tidal mudflats at low tide to feed. These invertebrates would also be susceptible to spray applications made to mudflats via potential contact exposure. The granular use would require standing water for dissolution to spatially disperse the active ingredient over the mudflat. With this in mind, EFED does not anticipate substantial contact exposure to terrestrial invertebrates from the use of Protector 0.5G at any point in the tidal cycle. However, the Protector 2F formulation warrants further evaluation based on the potential for exposure. Assuming an application of 2F at 0.5 lb a.i./A, terrestrial invertebrates could be exposed to direct sprays or to contact with contaminated sediments. EFED used the TREX arthropod scenario to evaluate an application of imidacloprid spray at 0.5 lb a.i./A to arrive at a contact EEC for terrestrial invertebrates on mudflats exposed to direct sprays. The EEC provided by TREX is 47 mg/kg bwt. For comparison, the honey bee contact LD_{50} is 78 ng/bee. A honey bee typically weighs approximately 0.128 g[16]. Consequently, 47 mg/kg bwt multiplied by 0.000128 kg (bee bodyweight converted to kilograms) equates to 6 µg a.i./bee, which is nearly two orders of magnitude greater than the LD_{50} and exceeds the level of concern of 0.4 for bees[17].

Another potential pathway of exposure involves direct contact with contaminated sediments when terrestrial invertebrates move to the mudflats at low tide when sediments are exposed. Imidacloprid applications would involve an application rate of 0.5 lb a.i./A. This rate was evaluated in a study that examined the toxicity of residues on foliage using the honey bee (MRID 42632901). The study found that imidacloprid has a residual toxicity of 8 hrs on foliage contaminated by direct spray, indicating that mortality will exceed 25% of the test organisms within a timeframe less than 8 hrs after application. Consequently, the surface of the mudflat sediment could remain very toxic to terrestrial invertebrates that move to the mudflats until the tide returns following applications of Protector 2F to exposed mudflat surfaces.

Similar to the assessment with birds and mammals, there is uncertainty in the use of TREX to evaluate risk concerns for terrestrial invertebrates on mudflats. The exposure values in TREX were derived from measurements on terrestrial arthropods in terrestrial environments. It is unclear how well these estimates in TREX correspond to actual residue levels on mudflat

---

[16] Mayer, D. & C. Johansen. 1990. *Pollinator Protection: A Bee & Pesticide Handbook*. Wicwas Press. Cheshire, Conn. p. 161

[17] US EPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees.

invertebrates following direct exposure to spray applications. In addition, the study on the toxicity of residues on foliage evaluated applications in a terrestrial environment to dry foliage. It is uncertain how well the residues on foliage in a terrestrial environment correspond to residues on the surface of a mudflat.

Without additional data specific to applications on mudflats to address these sources of uncertainty, current evaluations of exposure and the hazard described by the RT_{25} indicate concerns for terrestrial invertebrates other than bees due to applications of Protector 2F only to exposed mudflat surfaces. These invertebrates also represent the base of the food chain and are important to ecosystem functioning. However, it is also important to note that imidacloprid applications are only permitted according to the proposed label once per year at 0.5 lb a.i./A. Therefore the risk would only be present for a short duration prior to the next inundation, so the period of concern would last only a couple of hours.

Summary of Risks to Terrestrial Organisms

In terms of terrestrial taxa, risk is only present for the flowable formulation but not the granular formulation. For the granular formulation (Protector 0.5G), the avoidance behavior exhibited by birds, the unlikely consumption of granules by larger mammals feeding in the mudflats, and the requirement that the granules dissolve on the mudflats to lead to surface residues leads EFED to conclude that the granular use on exposed or inundated mudflats will not pose a risk concern for terrestrial taxa. For the flowable formulation (Protector 2F), EFED found no risk to mammals, and the risk to birds appears to be for applications of Protector 2F at low tide to exposed mudflat surfaces. Similarly, the concern for terrestrial invertebrates other than bees also relates to the same application of Protector 2F to exposed mudflat surfaces. In summary, only applications of Protector 2F to exposed mudflat surfaces with or without vegetation (*e.g.*, eelgrass) pose a risk concern to terrestrial taxa, but this risk persists for a relatively short amount of time as inundation is expected to rapidly dilute the residues of imidacloprid. Based on preliminary data, this risk concern could be addressed by limiting applications of Protector 2F to periods when there is standing water over the mudflats. The data do not definitively answer the question of how much water should be on the bed though because measurements on eelgrass were not taken at various times immediately after application, but rather at 24 hours after application at the earliest time. The additional monitoring data that have yet to be submitted to the Agency may address this question.

Uncertainties and Additional Data Needs

Uncertainties

There are a number of uncertainties related to the proposed use of imidacloprid on oyster beds in Willapa Bay and Grays Harbor. First, there are uncertainties related to data submitted to EFSA but not to the Agency. These data include a variety of studies on the toxicity of parent imidacloprid and various degradates to aquatic invertebrates and an avian dietary toxicity study with the Japanese quail. EFED has reviewed the summaries provided in the EFSA report on

imidacloprid[18]. These summaries provide an overview of the findings by the European Agency; however, EFED has not been able to formally review the data from these studies and therefore the use of the results of these studies in the risk assessment contains some uncertainty.

A number of studies have been submitted to the Agency and are currently in review (MRIDs 43946601, 43946602, 43946603, 43946604, 44558901). These studies include acute toxicity data on the desnitro, urea, and 6-chloronicotinic acid degradates to *Hyallela azteca* and/or *Chironomus tentans*. EFED has conducted a preliminary review of these studies, and acceptability of these data do not appear to change the risk conclusions contained in the risk assessment. If the final reviews of these data provide additional information that alters the conclusions in the assessment, then EFED will revise its risk assessment as appropriate.

For aquatic taxa, there are currently no endpoints available for sediment toxicity to estuarine/marine benthic species. In the absence of data specifically for benthic estuarine/marine species, the data from mysid shrimp will be used as a surrogate. As shown by the data, mysid shrimp appear to be the most sensitive species to imidacloprid. However, there is uncertainty as to whether mysid shrimp would be more or less toxic than other benthic taxa. Using mysid shrimp as a surrogate may overestimate risk to benthic species, but the use of mysid data is likely a conservative approach to evaluating risk to both benthic and free-swimming organisms.

The environmental exposure potential to desnitro olefin imidacloprid is uncertain. Although desnitro olefin imidacloprid has not been identified in field studies reviewed by the Agency to date, it has been reported to have been found in some other field studies[19]. Imidacloprid degradation in many of the submitted laboratory and field environmental fate studies was slow enough such that the full extent of formation of degradation products was not determined and there remain uncertainties regarding the long-term potential for exposure to imidacloprid degradates.

Finally, as highlighted in the risk characterization sections, there is some uncertainty as to the modeling approaches using TREX to evaluate risk to terrestrial organisms. TREX was not validated using data from tidal estuarine systems, so there is uncertainty as to how well TREX residue estimates reflect those that may be on aquatic vegetation or invertebrates within the tidal system as found in Willapa Bay and Grays Harbor.

Additional Data Needs

There are a number of uncertainties that also translate into data needs related to the proposed use of imidacloprid on oyster beds in Willapa Bay and Grays Harbor. There is uncertainty related to actual exposure levels *in situ* at both on-site and off-site locations in pore water, sediments, and

---

[18]Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005.

[19] Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005.

[19] For a reference to these data see: http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2002_eva/IMIDA_EVjjb.pdf and http://ethesis.inp-toulouse.fr/archive/00000579/01/al_sayeda.pdf. Additional discussion is provided in Appendix A.

overlying water. Furthermore, while preliminary data have been submitted to the Agency regarding effects to the biotic community at on-site and off-site locations, additional data are needed to evaluate the potential for long-term effects to the biotic community. EFED anticipates that final reports for both the 2011 and 2012 seasons will be submitted to the Agency for review. These reports should include sampling of pore water, sediment, overlying water, and biotic community metrics at on-site and off-site locations. In addition to these EUP data, additional monitoring of concentrations over time in Willapa Bay and Grays Harbor would also help to address the uncertainty related to the persistence of imidacloprid and possible long-term concentrations in sediments. This additional monitoring may be addressed through the NPDES permitting process with the State of Washington. The monitoring data collected as part of the NPDES program should then be submitted to the Agency for review. These reports and additional data would provide a basis for further evaluating the conclusions in this assessment and assist EFED to confirm or eliminate potential concerns from the risk conclusions identified in this assessment.

Another area of uncertainty relates to the degradates and their toxicity to fish. Current EcoSAR estimates of toxicity from EPISUITE poorly estimate toxicity levels of parent imidacloprid, and may therefore be providing poor estimates of the degradates as well. It appears that EPISUITE is underestimating the toxicity of the parent imidacloprid by two orders of magnitude. If this same margin of safety (two orders of magnitude) is applied to the degradates of concern, the desnitro olefin, desnitro, and urea degradates remain a potential concern. At present EFED has not identified data on the desnitro olefin degradate and its rate of formation relative to the parent. Concerning the other two degradates, preliminary pore water data suggest that the urea and desnitro metabolites are likely forming. Monitoring data to be submitted from 2011 and 2012 EUP studies may address this uncertainty if levels of the chronic total residue levels in overlying water are undetectable. However, if the monitoring data reveal that these degradates form at relevant levels or if no data on these degradates are available, then additional toxicity information for these three degradates to saltwater fish would address this uncertainty. An acute toxicity test with sheepshead minnow (850.1075) using the appropriate degradates would provide an initial comparison with the parent compound. If the degradates appear to be more toxic than the parent compound, additional chronic testing (850.1400) may be warranted.

Appendix A. Environmental Fate and Transport

a. Degradation

Hydrolysis of Imidacloprid (161-1)–Imidacloprid was stable to hydrolysis in pH 5 and 7 buffer solutions, and slowly degraded at pH 9 with an extrapolated half-life of 355 days (MRID 42055337; EFGWB[20] review nos. 92-0210, 92-0196). No degradation products accumulated significantly during the course of the study.

Photolysis in water (161-2)– The only environmental fate study in which extensive degradation occurred within a period of hours or a few days was the aqueous photolysis study (MRID 42256376; EFGWB reviews no.92-0847, 92-1039, and 92-1042). The possibility of rapid photolysis has some obvious implications for surface water exposure, but should not be assumed to universally occur in surface waters because there is not supporting evidence from surface water monitoring studies, the photolytic rate can be substantially different from distilled water in natural waters, and the amount of pesticide actually exposed to sunlight can be quite low in many surface waters.

Imidacloprid degraded with an "environmental" half-life of 4.2 hours (0.2 days) in pH 7 buffer solutions maintained at 24EC[21]. The 50% and 75% disappearance times were approximately 1 and 2 hours, respectively.

Residue analysis. Thin-layer chromatography (TLC) in multiple solvent systems and radiometric detection (exposure of TLC plates to X-ray film) was used to confirm the identity of imidacloprid and two degradation products. In addition, residues were also determined with reverse phase high-performance liquid chromatography (HPLC). A linear analyzer was used to quantify residues eluted on TLC plates. Imidacloprid guanidine / desnitro was the most prominent degradate, accumulating to 17% of the applied imidacloprid at the last sampling interval 2 hours after treatment. The only other degradation product that was identified was imidacloprid urea, which constituted 10% of the applied material 2 hours posttreatment. No effort was made to carry the experiment on to follow the degradation of imidacloprid more completely, and other degradation products were not identified. Two other separated, but unidentified photodegradation products reach maximum levels of 13% and 8% of the applied imidacloprid when the experiment was terminated after 2 hours of irradiation.`

The initial concentration of imidacloprid was 5.4 mg/l (5400 ppb) in sterile, buffered solution. The study was conducted with a Xenon lamp rather than natural sunlight (the study summary mentions that "under natural sunlight 60% of the compound were [sic] degraded after 4 hours", but a detailed description of the natural sunlight experiment was not provided). The light intensity of the lamp was 8.9 to 9.5 uW/cm^2 compared to 4.1 to 5.3 uW/cm^2 for "sunlight intensity on bright days" at the Yuki Institute in Japan, where the experiment was apparently conducted. Imidacloprid was shown to be more stable in sterile solution kept in the dark, but the

[20]EFGWB = Environmental Fate and Ground Water Branch, later disbanded and blended into the Office of Pesticide Program's reorganized Environmental Fate and Effects Division.

[21]A first-order degradation half-life of 57 minutes was calculated from the study, then assumptions were made to recalculate what the half-life should have been under normal intensity sunlight.

last sample was taken only after two hours.
This study failed to identify most of the residues by two hours after application, and also failed to demonstrate the long-term stability of imidacloprid in the dark control. Although the stability of imidacloprid at pH 7 in solution has been demonstrated in a separate hydrolysis study, this should have been confirmed in the exact same solution that was used for the photolysis study. A further limitation was that the long-term stability of imidacloprid degradation products to photolysis was not evaluated.

The primary degradation products resulting from aqueous photolysis reported in the literature by Moza et al. (1998[22]) are as follows:

- imidacloprid urea
- 6-chloronicotinic aldehyde
- 6-chloro-N-methylnicotinacidamide
- 6-chloro-3-pyridyl-methylethylenediamine

Photolysis on soil (161-3)– Imidacloprid degraded with a registrant-calculated second-order half-life of 39 days (calculated environmental half-life of 171 days). Two experiments were run, one for 5 and the other for 15 days. At the end of the 15 days, imidacloprid parent accounted for 81.6% of the applied radioactivity; consequently an accurate estimate of the degradation rate under the conditions of this test is not possible.

Aerobic soil metabolism (162-1)–Imidacloprid degraded in a Kansas sandy loam soil (series name or classification unknown; MRID 421073501) with a half life well over 1 year (the duration of the study), extrapolation of the data with assumption of continued decay at a first-order rate results in a calculated half-life of 660 days (Table E-1). In contrast, in three European soils (MRID 452393), the first-order half-lives were calculated to be 248, 341, and 188 days[23]. The mean first-order half-life was 359 days (90% upper bound confidence value of 520 days); however there appeared to be greater persistence during the latter part of these studies than predicted by a simple first-order model. These studies were conducted at 20 C (except 22 C for the Kansas soil), persistence might have been lower at 25 C, the temperature of most laboratory soil metabolism studies.

Table A-1. Summary of aerobic soil metabolism studies for imidacloprid.

Soil	% O.C.	pH in water/ 0.01 M CaCl2	% Remaining at end of study	Extrapolated half-life, days
BBA 2.2 lehmiger loamy sand (meadow soil from Hanhofen, Vorderpfalz, West Germany (MRID 452393-01; Miles #100140)	2.2	6.3/ 5.5	63.3 (100 days)	188
Hoefchen silt loam (MRID 452393-02; Miles #100141)	1.2	ND/ 5.3	66.8 (100 days)	248

[22] Moza, P.N., K. Hustert, E. Feicht, and A. Kettrup. 1998. Photolysis of imidacloprid in aqueous solution. Chemosphere. 36(3): 497–502.

[23]Studies with the BBA 2.2, Hofchen, and Monheim soils were conducted at 20 C with the soil water content kept at 40% of "water capacity". The Kansas soil study was conducted at 20 C and 75% of 1/3 bar moisture level, the 1/3 bar water content was 14.7%.

Monheim 1 sandy loam (MRID 452393-03?; Miles #101955)	1.3	?	? (100 days)	341
Kansas sandy loam (MRID 42073501, Miles #101241)	1.4	6.5/ 4.8	61.6 (366 days)	660

Under aerobic conditions no specific compound has been identified as accumulating to 10% or more of the applied in soil or water. The lack of identification of major degradates was a factor of both the limited transformation of parent compound over the duration of these studies and the failure to identify the nature of much of the residues. Anhalt et al. (2007) have reported that imidacloprid desnitro/guanidine and imidacloprid urea were products of degradation by soil microbes[24]. In studies conducted by the registrant to support registrations in Europe all degradates looked for, including the urea and desnitro / guanidine metabolites were always detected at less than 10% of the applied imidacloprid[25] (these data have not been reviewed by EPA).

Anaerobic soil metabolism (162-2)-- No anaerobic soil metabolism study has been conducted; however, an anaerobic aquatic soil metabolism study was conducted in lieu of this study.

Anaerobic aquatic soil metabolism (162-2)-- Imidacloprid degradation was evaluated in a water / sediment mixture (obtained from a pond in Stilwell, Kansas) (MRID 42256378).Characteristics of the sediment were: silt loam textural class (14% sand, 58% silt, 28% clay), 3.2% organic matter, pH 6.9. The pond water was not characterized. The study was conducted with 500 ml pond water and 100 g of sediment in flasks under unspecified conditions; imidacloprid was added to the overall system at a concentration of 0.56 ppm (presumably part per million by weight). The incubation flasks were purged with nitrogen and the maintenance of anaerobic conditions was documented with periodic measurement of redox potential, pH, and oxygen concentration. Imidacloprid degraded with a first order anaerobic half-life of 27 days over the 358-day post-application incubation period. Under the anaerobic conditions of this study, imidacloprid underwent a nitro-reduction reaction to the degradate imidacloprid guanidine / desnitro, a compound which accumulated to 66% of applied 249 days after application of parent imidacloprid. Imidacloprid guanidine / desnitro appears to be extremely persistent under anaerobic conditions; residues of this degradate still represented 64% (50% in the sediment and 14% in the water) of the applied imidacloprid at the last sampling date of 358 days posttreatment. Virtually no mineralization of imidacloprid occurred, evolved carbon dioxide represented less than 0.2% of the applied imidacloprid.

b. Mobility

Mobility/Adsorption/Desorption (163-1)--Based on two sets of batch equilibrium studies

[24] Anhalt, J.C., T.B. Moorman, and W.C. Koskinen. 2007. Biodegradation of imidacloprid by an isolated soil microorganism. Journal of Environmental Science and Health Part 8; 42:509-514.

[25] See: Anderson, C. and Fritz, R. 1990a. Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions. Bayer AG, Report No. PF3322. Date: date: 1990-12-07. Amended 1992-10-01. (not submitted to EPA).

Anderson, C. and Fritz, R. 1990b. Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions. Bayer AG, Report No. PF3434, Date: 1990-01-19. Amended: 1992-10-01. (not submitted to EPA.

(MRID 420553-38 - American soils; and M in a total of eight soils (four American and four German), parent imidacloprid is moderately mobile with Freundlich adsorption coefficients ranging between 0.96 and 4.76. Soil organic carbon partition coefficients (Koc) values did not vary greatly, the range for eight soils was 132 to 256 ml/g (161 to 239 for the four American soils) with an average Koc of 178. Results for the American and German soil studies are given in Tables E-2 and E-3, respectively. Several articles reflecting further research on imidacloprid sorption in soil have since been published in the open literature, which provide insight into topics such as the increased sorption observed with time and also with lower initial concentrations of imidacloprid in soil water. Sorption coefficients measured in published studies are generally in the same range as the registrant-submitted studies, at least over the short-term (Oi, 1999, Cox et al. 1998).

Table A-2. Imidacloprid parent adsorption coefficients in American soils (MRID 425208-01).

Soil type	K_{ads}	1/N	%OC	Koc
sand	0.96	0.78	0.4	239.0
loamy sand	1.02	0.88	0.6	170.0
silt loam	4.18	0.78	2.6	160.8
loam	3.45	0.76	2.0	172.5
silt loam w/Na azide*	4.76	0.73	2.6	183.1
*Same soil as the silt loam, amended.				

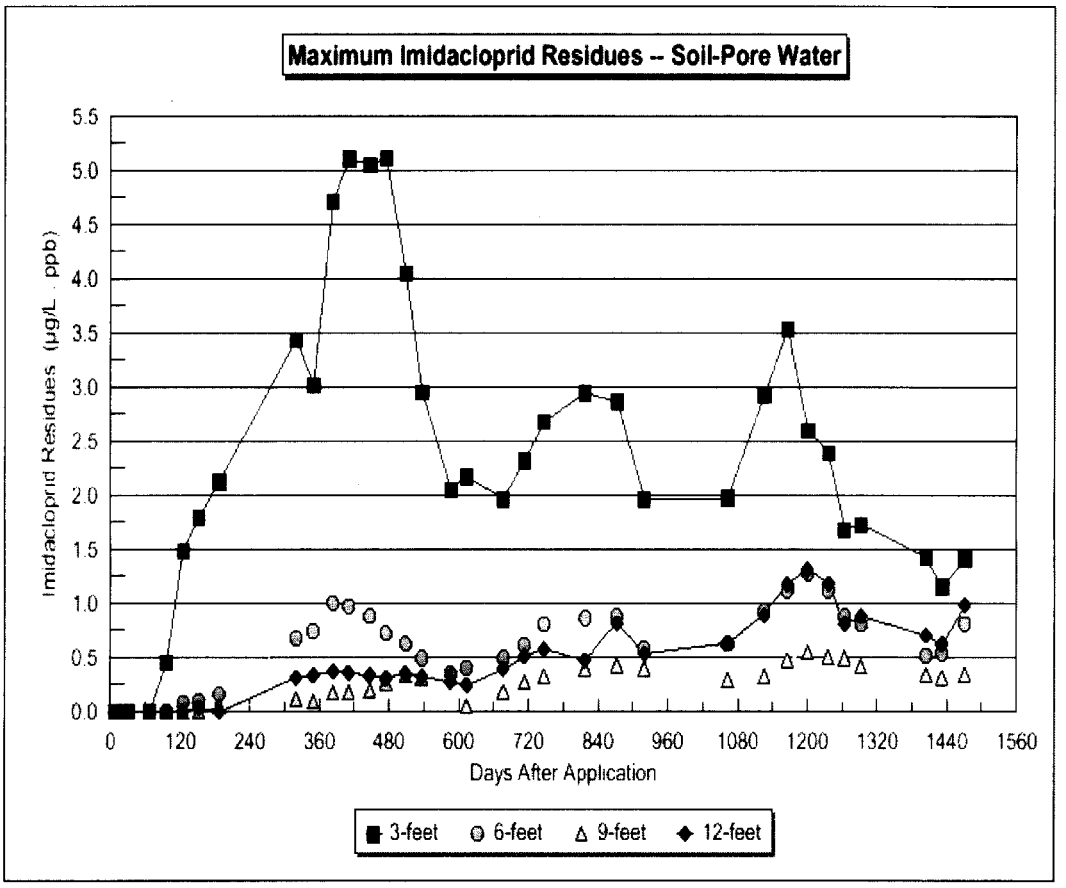


Figure A-1. Imidacloprid Small-Scale Prospective Ground-Water Monitoring Study in Michigan: results through the first 1500 days: Maximum residues found in soil pore-water at 3, 6, 9, and 12-foot depths.

Table A-3. Imidacloprid parent adsorption coefficients in German soils (MRID 420553-38).

Soil type	Kads	1/N	%OC	Koc
sandy loam	3.59	0.74	1.4	256.4
Hofchen silt	2.38	0.83	1.8	132.2
low humus sandy	1.17	0.78	0.8	156.0
Ranschbach silty clay	1.36	0.85	0.6	212.5

In addition to the above-mentioned studies, an aged soil column leaching study with imidacloprid parent (MRID 420553-39) and an adsorption / desorption study with imidacloprid guanidine / desnitro (MRID 425208-02) have been completed. In the imidacloprid guanidine / desnitro study the same four American soils were studied as with the parent compound (compare Table E-4 with Table E-2). The degradate was more strongly adsorbed than parent imidacloprid in all four of the test soils.

Table A-4. Imidacloprid guanidine / desnitro adsorption coefficients in American soils (MRID 425208-02).

Soil type	K_{ads}	1/N	%OC	Koc
sand	0.76	1.22	0.23	327.0
loamy sand	2.91	1.09	0.35	833.0
silt loam	14.20	1.02	1.51	942.0
loam	10.15	0.82	1.16	866.0

Prospective ground-water studies have been conducted at two locations and in both cases the predominant compound detected in soil, soil-pore water throughout the vadose zone, and in ground-water (when detectable) was parent imidacloprid. Of the three degradates analyzed for (imidacloprid guanidine / desnitro, olefin, and urea derivatives) only imidacloprid urea leached at concentrations that were frequently detectable (minimum detection limit of 0.02 ug/L).

There is a possibility that exposure to these degradates could be significant. Therefore, it is important that either specific analytical methods for the degradates or some sort of total residue method for residues in water and soil samples should be developed and made publicly available (specific methods would be required for any degradate identified as being of toxicological concern).

c. Accumulation

Accumulation in Laboratory Fish (165-4) This data requirement has been waived. Octanol/water partitioning (Kow) data provided by the registrant implies a low potential to bioaccumulate (Kow for imidacloprid = 3.7 @21 C).

d. Field Dissipation

Terrestrial field dissipation (164-1). Terrestrial field dissipation studies have been submitted from Georgia (loamy sand, bare ground), Minnesota (sandy loam, planted to corn), California (sandy loam, planted to tomatoes), Minnesota (loam, turf plot), and a Georgia loamy sand (turf plot) (Table E-5). The dissipation half-lives (based on analyses of 0-6 inch soil cores only) ranged from 107 days to much greater than 1 year (no significant dissipation over the one year of the study at three of the sites). In each of these studies a single or broadcast application at 0.5 lb a.i./A was made.

Table A-5. Dissipation of imidacloprid in five field studies (a single application at 0.5 lb a.i./ A was made in each study).

Study Identification	Crop	Concentration at time Zero, ug/g, or maximum concentration	Concentration after 1 year, ug/g	Calculated Half-life, days
Tifton, Georgia loamy sand	bare-ground	0.11	0.05	>365
Hollandale, Minnesota sandy	field corn	0.095	0.073	>> 365

loam				
Fresno, California sandy loam	tomatoes	0.15	0.013	146
Tifton, Georgia loamy sand (0-3 in. soil samples)	Bermuda grass turf	0.17 (28 & 63 D.A.T.)[26]	0.12 (126 D.A.T.)	107 (based on composite analyses of turf and soil)
Waseca, Minnesota loam (0-3 in. soil samples)	bluegrass turf	0.05 (60 D.A.T.	0.038 (120 D.A.T.)	>120 (based on composite analyses of turf and soil)

In each of these studies the registrant failed to confirm the application rate [see earlier EFGWB, EFED review dated approximately February 1993: "'NTN 33893' (insecticide) - New Chemical terrestrial non-food, turf, ornamentals"] and did not evaluate the formation and decline of any degradation products.

Field dissipation studies have been cited in reports by international regulatory agencies but not submitted to EPA and could potentially contain useful information on imidacloprid degradation. For example, it has been noted[27] that the following studies contain field residue data for imidacloprid desnitro olefin:

Philpot, J.D. and Yen, P.Y. 1998. Terrestrial field dissipation of imidacloprid on turf in Ontario, Canada, 1994. Bayer Corporation, Stilwell, KS, USA. Bayer AG, Report No. BR107817. Date: 1998-01-15. Unpublished.

Formella, T.M. and Cink, J.H. 1997. Imidacloprid (NTN 33893) turf dissipation in North Carolina, 1992. Bayer Corporation, Kansas City, MO, USA. Bayer AG, Report No. BR107384. Date: 1997-04-18. Unpublished.

e. Special Field Studies

Small-Scale Prospective Ground-Water Monitoring Studies (164-1).

The registrant has conducted two small-scale Prospective Ground Water Monitoring studies: one each in Montcalm County, Michigan and Monterey County, California. In both studies, the registrant monitored for imidacloprid parent, imidacloprid guanidine / desnitro, imidacloprid olefin, and imidacloprid urea in the vadose zone and in shallow ground water.

In the California study (located near Salinas, Monterey County) imidacloprid was applied at 0.45 lb a.i./A within the planting furrow (broccoli crop) in July 1996. At this site, more leaching of imidacloprid residues was found to occur in the "control" plot than in the treated area. The registrant believes the imidacloprid found in control plot samples is from four foliar applications of imidacloprid in 1995 and 1996. Although it appears that sufficient irrigation water was applied at this site to facilitate some ground-water recharge, interpretation of this study is complicated by the relative insensitivity of the analytical method for the conservative tracer

[26]D.A.T. = days after imidacloprid treatment.

[27] See: http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2002_eva/IMIDA_EVjjb.pdf and http://ethesis.inp-toulouse.fr/archive/00000579/01/al_sayeda.pdf

(bromide) to be used to confirm this. In fact, there were only a handful of detections of bromide in the first 3+ years of sampling of ground water, providing no definitive evidence that sufficient water has been applied at the site for any pesticide residues of any kind to reach ground water (because little or no infiltration of water had occurred). Our conclusion therefore is, that even though there were only a few detections of imidacloprid in ground water (the highest at 0.09, 0.10 and 0.14 ppb) and the method has a claimed ability to quantitative imidacloprid at 0.01 ppb in water samples (although apparently only detections above 0.05 ppb were reported), there still could be substantial potential for imidacloprid to leach to ground water following application to irrigated vegetable or fruit crops in California (if sufficient water is added and time allowed for the aquifer to be recharged with water from the surface posttreatment). Additionally, we note that all three of the imidacloprid degradates were detected leaching through the vadose zone and there were also a few detections of imidacloprid urea in ground water at the California study site.

In the Michigan study (located near Vestaburg, Montcalm County) imidacloprid was applied at 0.34 lb a.i./A by an unspecified method (potato crop) May 31, 1996. Imidacloprid was found to be leaching at a variable rate and concentration in all six of the lysimeter clusters with residues occasionally exceeding 1 ppb at 12 feet, the lowest depth sampled (Figure 2). In the Michigan study (planted to potatoes), imidacloprid was found to be leaching at a variable rate and concentration. Detectable residues of imidacloprid occurred in all six, and in four out of six on-site lysimeters at the three and six foot depths, respectively, by 319 days after treatment (DAT 319), at concentrations up to 3.35 ppb.

Residues in ground water at the Michigan site were up to 0.24 ppb (Figure 3). Complete breakthrough into ground water was not clearly been observed; consequently it is possible that higher concentrations of imidacloprid in ground water could be observed under use conditions which promote more ground-water recharge and/or when imidacloprid is used in multiple growing seasons at the same site. Imidacloprid parent was consistently detected in one of six monitoring well clusters in the treated field beginning about 500 days after application and continuing through the close of the study some 5 years after application. No degradation products were detected in ground water during this period (there were a very few detections before application that may have been due to previous uses nearby or sample contamination). The 0.24 ppb level might increase slightly over time if imidacloprid continued to leach into groundwater (and be applied in at least some of the subsequent growing seasons); however, the level probably would not increase dramatically given that the maximum levels seen at the three and twelve foot soil depths were 1.63 ppb and 1.31 ppb, respectively.

Data from the California site is less useful due to the fact that there appears to have been very little ground-water recharge occurring during the course of the study as evidenced by the almost complete lack of detection of the bromide tracer (applied concurrently with imidacloprid) in ground water (bromide residues in ground water never consistently and reliably exceeded the measured background levels). The maximum combined residue of imidacloprid parent and degradates found in the suction lysimeters was 0.62 ppb at 633 days post application. The maximum combined imidacloprid residue in the ground water at the California site was 0.14 ppb found 149 days post application. EPA concluded that low (sub-ppb) level contamination of potable ground water might occur in this region following application to irrigated vegetable or fruit crops.

*f. **Other (non-registrant) Ground-Water Monitoring***

EPA has received several reports summarizing monitoring of ground water that is vulnerable to contamination in New York state (primarily Long Island). Much of this monitoring was targeted to areas with known histories of imidacloprid use and previously documented ground-water contamination issues. Suffolk County Department of Health Services reports that there were 27 detections of imidacloprid above a detection limit of 0.2 ppb in about 5,000 samples (Electronic mail communication from Sy Robbins Suffolk County Department of Health Services, Bureau of Groundwater Resources), 1/16/2004 to Michael R. Barrett, (US EPA, Office of Pesticide Programs Environmental Fate & Effects Division).

More recently, imidacloprid has been found in domestic drinking water wells in New York state:

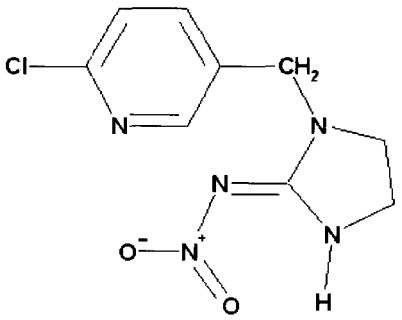
> "To date, imidacloprid has been detected at concentrations (0.2 to 7 ppb) in 12 monitoring wells and 16 down gradient private homeowner wells. Imidacloprid has also been recently detected at 0.24 ppb in two Suffolk County community water supply wells (85 feet and 90 feet deep)." (Imidacloprid NYS DEC Letter - Registration of New Imidacloprid Products in New York State as Restricted-Use Products 10/04)

EFED received background information on three high detections in drinking water that might indicate unusual conditions associated with each detection. The first of these wells is a private well in Mattituck, Long Island in which imidacloprid was found at a level of 6.69 ppb. An investigation by the New York authorities, concluded that these high levels were due to misuse of the pesticide in a greenhouse adjacent to the well where imidacloprid contaminated water was drained onto the ground in the immediate vicinity of the well. The second well was one of five shallow monitoring wells installed directly down gradient from imidacloprid use sites for the purpose of monitoring pesticide levels. One of those wells, "Jamesport B-2", showed levels of imidacloprid as high as 2.06 ppb. It was discovered, however, that this well was in all likelihood contaminated as a result of a manmade sump nearby that was constructed to alleviate ponding in the field and directly connected surface water to ground water.

Imidacloprid has been detected in shallow ground water wells directly downgradient from a site investigating use of tree injection treatments of imidacloprid. The highest level of imidacloprid found in these wells was 3.9 ppb. These wells, however, are not representative of wells used to supply ground water for drinking water. The wells were screened at extremely shallow depths (screens beginning only 4 to 10 feet from surface) due to the fact that the depth to ground water averaged about five feet. It was concluded by the researchers (EFED makes no comment on this at this time without further investigation ourselves) that these wells are "no more representative of what would likely occur in drinking water supplies than pesticide concentrations in samples taken from a weir draining an agricultural field are representative of what would occur in a community water supply drawing from a river or reservoir downstream."

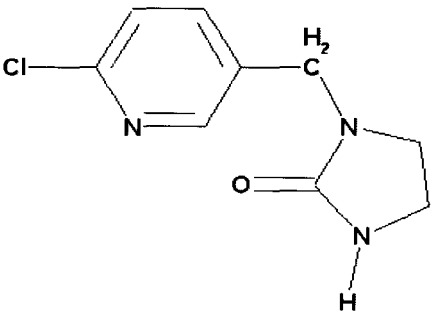
In a small turf plot surface water monitoring study by the registrant, the plot received from 1.7 to 3.5 in. water per hour for two hours. Up to 20% of the applied imidacloprid was found in runoff water 24 hours after application.

Appendix B. Structures of Imidacloprid and Selected Degradates



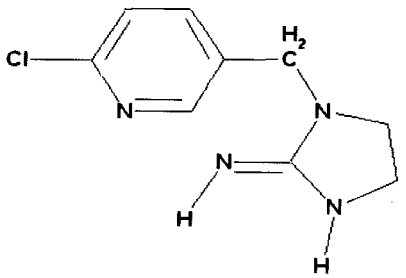
Imidacloprid (parent)
NTN 33893
IUPAC Name: (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine
CAS Name: (2E)-1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine
CAS No.: 138261-41-3

Formula: $C_9H_{10}ClN_5O_2$
MW: 255.7 g/mol
SMILES:
c1nc(Cl)ccc1CN2C(=NN(=O)=O)NCC2

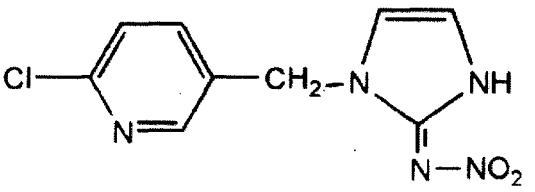


Imidacloprid Urea, I. 2-Ketone.
DIJ 9817; M12 (EU)
Name: 2-Imidazolidinone,1-[(6-chloro-3-pyridinyl)methyl]-
CAS No: 120868-66-8

Formula: C9H10ClN3O



Imidacloprid Guanidine; Desnitro Imidacloprid
NTN 33823 (Guanidine ; NTN 38014; WAK 4140; WLF 230; BEG 5322; Imidacloprid M09 (EU)
IUPAC Name: 1-[(6-Chloro-3-pyridyl)methyl]imidazolidin-2-imine
Other Name: 1-(6-chloro-3-pyridylmethyl)imidazolidin-2-ylideneamine



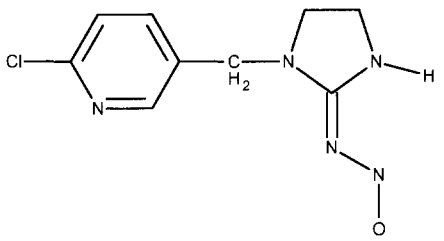
Imidacloprid olefin
NTN 35884; GAJ 2269; Imidacloprid M06 (EU)
Name: 1H-Imidazol-2-amine,1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-
CAS no.: 115086-54-9

Formula: $C_9H_8ClN_5O_2$

CAS no.: 115970-17-7

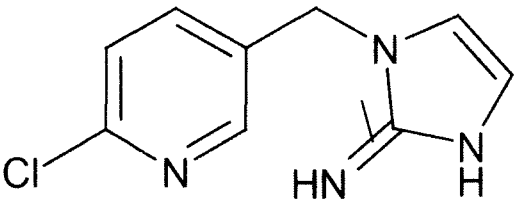
Formula: $C_9H_{11}ClN_4$
MW: 210.66 g/mol
SMILES: [H]/N=C/1\NCCN1Cc2ccc(nc2)Cl

May be present as free base (pictured) or associated with an acid such as HBr or H_2SO_4



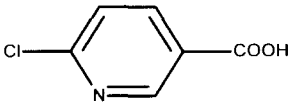
Imidacloprid nitrosimine
NAK3839
Name: N-[(E)-[1-[(6-chloro-3-pyridyl)methyl]imidazolidin-2-ylidene]amino]hydroxylamine

Formula: $C_9H_{10}ClN_5O$



Imidacloprid desnitro olefin
ANC 2126; Imidacloprid M23 (EU)
Name: 1-(6-chloro-3-pyridylmethyl)-4-imidazolin-2-ylidenediamine

Formula: $C_9H_9ClN_4$



6-Chloronicotonic acid
BNF 5518A
IUPAC: 6-Chloronicotinic acid
CAS No.: 5326-23-8

Formula: $C_6H_4ClNO_2$
MW: 157.56 g/mol
SMILES: O=C(O)c(ccc(n1)Cl)c1

Appendix C. Aquatic Exposure Modeling Inputs and Results

To estimate the amount of exposure to imidacloprid and, in some cases, imidacloprid total residues over time all of the available monitoring data were referred to, but the 2010 soil pore water monitoring results were most heavily relied upon. These data have limitations, for example, the enzyme linked immunosorbent assay (ELISA) analytical method is not entirely specific for imidacloprid (but the most cross-reactivity of the assay is expected to be associated with imidacloprid degradation products in the estuaries, which are also of some interest with regard to aquatic exposure[28].) In one report, the researchers provide evidence that analysis of the initial soil core samples taken within a few days after treatment might be overestimated imidacloprid residues due to matrix interference in the assay (Grue, 2012). Nonetheless, because of the potentially rapid motion and uneven distribution of imidacloprid residues over time, and because numerous environmental fate studies indicate there may be an increased association of imidacloprid residues with soil organic carbon or certain minerals with significant absorption / cation-exchange capacity, it is expected that the longest and most consistent residence time of imidacloprid residues should be in the soil-pore water.

In this study sediment cores were taken to a depth of 10 cm (with some additional cores taken to a depth of 25 cm to confirm whether most of the imidacloprid residues resided in the top 10 cm of sediment (which they seemed to do so since the concentrations in the 25 cm cores were much lower than in the corresponding 10 cm cores; the complete 25-cm data are not yet available, however). Initial sampling was done immediately the applications of imidacloprid at the lowest of the low tides of the day. The depth of standing water, if any, at the time of initial application and sampling was not specified, however. For the purposes of modeling expected concentrations at specific depths of incoming tidal water the measured concentrations in soil pore water (90% upper bound confidence limit of the mean) over time were used as the basis for estimating the mass of imidacloprid available for partitioning into the standing tidal waters.

For the purposes of modeling expected concentrations at specific depths of incoming tidal water the measured concentrations in soil pore water (90% upper bound confidence limit of the mean) over time were used as the basis for estimating the mass of imidacloprid available for partitioning into the standing tidal waters.

"From a theoretical perspective, the application of 2 lbs a.i. per acre to a given area will result in a total deposition of 0.224 g a.i. per m_2 within the treatment area. At this deposition rate, depth of sediment cored, specific gravity, and the percent moisture of samples collected in this study, we would anticipate a theoretical maximum whole dry sediment measure of 1,556 ppb. Conversely, under the presumption that 100% of the IMI is solubilized in the water fraction, pore water measures should not exceed 5,013 ppb. For the 0.5 lb a.i./ac application, these values would be one quarter of those calculated for the 2 lb application: 389 ppb and 1,253 ppb, respectively. See Appendix C for calculation of theoretical values." (page 7 of 2010 sediment report.)

[28] For the three metabolites examined, Imidacloprid Olefin, DesNitro Imidacloprid, and Imidacloprid Urea the cross-reactivities were 32, 60 and 34%, respectively.

Imidacloprid Monitoring Data Summary and Use in Oyster Bed Exposure Estimation

The following non-guideline studies were received from the registrant (only the study by Felsot and Ruppert (2002) has been published):

"Appendix A: Field trials of imidacloprid against burrowing shrimp, 2011".
[This is a preliminary report on the results of the 2011 residue and effects monitoring; a full citation was not available and the data provides were preliminary and incomplete. Additional review of the 2011 data may be warranted when a complete report is formally submitted to the Agency. This report is expected to provide further information on the concentrations of imidacloprid in the water column, pore-water, and in sediments arising from applications to oyster beds. The report is also slated to provide further validation of the precision and accuracy of an ELISA analytical technique compared to the standard HPLC technique.]

Grue, Christian E.; J. Martin Grassley, John A. Frew, and A. Troiano. 2012. Use of an Enzyme--linked Immunosorbent Assay (ELISA) to Quantify Imidacloprid in Sediment Pore Water Following Application of Imidacloprid in Willapa Bay, Washington – Matrix Effects and Cross--reactivity. University of Washington unnumbered report.
[This report provided information on the sensitivity of the ELISA analytical method to imidacloprid metabolites which is used in this review to provide conservative estimates of chronic exposure to imidacloprid total residues based upon the ELISA 2010 monitoring results.]

Grue, C.E., J.M. Grassley, and J.A. Frew. 2011. Concentrations of imidacloprid in sediment pore water following application of imidacloprid in Willapa Bay, Washington - 2010. Report submitted to the Willapa Grays Harbor Oyster Growers Association. Washington Cooperative Fish and Wildlife Research Unit, University of Washington, Seattle, WA. 22 pp. (November 11, 2011).
[This report only contains results from monitoring with an ELISA method. The ELISA method, while unable to completely resolve the nature of the detected residues (because of cross-reactivity with imidacloprid degradates) has advantages for provide a conservative Tier 1 estimate of exposure from this use.]

Grue, Christian E. 2012. Use of an enzyme---linked immunosorbent assay (ELISA) to quantify imidacloprid in sediment pore water following application of imidacloprid in Willapa Bay, Washington – Matrix effects and cross---reactivity. University of Washington Seattle, WA Prepared for: Willapa Grays Harbor Oyster Growers Association (3/12/2012).

Felsot, A.S. and J.R. Ruppert. 2002. Imidacloprid residues in Willapa Bay (Washington State) water and sediment following application for control of burrowing shrimp. J Agric. Food Chem. 50:4417-4423.
[An earlier study with limited sampling of imidacloprid in standing water and sediment at 0-1, 14, and 28 days post-application to small plots. Also includes measurement of imidacloprid sorption coefficients directly in a Willapa Bay sediment sample mixed with sea water.]

[This is the published version of an earlier monitoring study.]

Moore, J. and D. Tufts. 2011. Willapa-Grays Harbor Oyster Growers Association 2011 annual report for burrowing shrimp control. Report submitted to the Washington State Dept. of Ecology (December 1, 2011).
[This report has apparently complete reports of the carbaryl residue monitoring done for the 2011 carbaryl applications, but only has "Preliminary Findings" regarding the 2011 imidacloprid Experimental Use Permit application in a section entitled "Appendix A: Field trials of imidacloprid against burrowing shrimp, 2011".]

Giddings, Jeffrey M.; Larry Turner, Jim Gagne, and Gary Dickson. 2011. Ecological Risk Assessment of Imidacloprid Applications to Control Burrowing Shrimp in Oyster Beds of Willapa Bay and Grays Harbor, WA. Compliance Services International (CSI) project 11706, Lakewood, WA; submitted to Washington State University under Subcontract no. 19303. (June 17, 2011 Draft report.)
[This report provides an overall summary of the available data for imidacloprid monitoring in the water above and near treated beds as well as in sediment pore water and will be cited in this review as appropriate.]

&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&&

&&&&&&&&&&&&&&&&&&&&&&&&&&

Source Code for Program (KDCALC) Used to Estimate Partitioning of Imidacloprid into Standing Water of Incoming Tides

```
      PROGRAM KDCALC

C     THIS IS A PROGRAM TO CALCULATE THE PESTICIDE CONCENTRATION IN
C     WATER COLUMN AND THE PESTICIDE CONCENTRATION IN SEDIMENT BASED
C     ON THE ADSORPTION COEFFICIENT (Kd), THE DEPTH OF THE WATER AND
C     THE DEPTH OF SEDIMENT - CALCULATION IS BASED ON A 1.0 SQUARE
C     METER SURFACE AREA
C
      REAL APRATE,KD,DEPWAT,DEPSED,CONWAT,CONSED,MASWAT,MASSED,VOLWAT,
     2     VOLSED,PSTTOT,PSTSED,PSTWAT,BDSED,BDWAT,KDCHEK,TOTCHK
C
      INTEGER CODE
      CHARACTER*1 AGAIN
      CHARACTER*20 OUTFIL
C
C     DESCRIPTION OF VARIABLES
C
C     APRATE   APPLICATION RATE IN KG/HA
C     AREA     AREA OF THE SYSTEM = 1.0 SQUARE METERS
C     BDSED    BULK DENSITY OF THE SEDIMENT = 1,650 KG/M3
C     BDWAT    BULK DENSITY OF WATER = 1.0 KG/LITER
C     CONSED   INSTANTANEOUS CONCENTRATION IN THE SEDIMENT
C     CONWAT   INSTANTANEOUS CONCENTRATION IN THE WATER COLUMN
C     DEPSED   DEPTH OF THE SEDIMENT LAYER
```

```
C     DEPWAT   DEPTH OF THE WATER COLUMN
C     KD       SOIL ADSORPTION COEFFICIENT
C     MASSED   MASS OF SEDIMENT
C     MASWAT   MASS OF WATER
C     PSTTOT   TOTAL MASS OF PESTICIDE IN THE SYSTEM = APRATE * DECDRF
C     PSTSED   MASS OF PESTICIDE IN THE SEDIMENT
C     PSTWAT   MASS OF PESTICIDE IN THE WATER
C     DECDRF   DECIMAL FRACTION SPRAY DRIFT
C     PCTDRF   PERCENT SPRAY DRIFT
C     VOLSED   VOLUME OF SEDIMENT
C     VOLWAT   VOLUME OF WATER
C
      WRITE(*,5)
    5 FORMAT(////,3X,'                                KDCALC          ',/////
     2 3X,'           ENVIRONMENTAL FATE AND EFFECTS DIVISION         ',/
     3 3X,'                OFFICE OF PESTICIDE PROGRAMS               ',/
     4 3X,'            U.S. ENVIRONMENTAL PROTECTION AGENCY          ',//
     5 3X,'                          VERSION 1.0                      ',/
     6 3X,'                          OCT 1, 2002                       ')
C
      WRITE(*,10)
   10 FORMAT(//,3X,'THIS IS A PROGRAM TO CALCULATE THE PESTICIDE CONCENT
     2RATION',/
     3 3X,'IN THE WATER COLUMN AND IN THE SEDIMENT LAYER BASED ON THE',/
     4 3X,'AMOUNT APPLIED, THE ADSORPTION COEFFICIENT (Kd), THE DEPTH',/
     5 3X,'DEPTH OF THE WATER COLUMN AND THINKNESS OF THE SEDIMENT LAYER
     6',/
     7 3X,'CALCULATION IS BASED ON 1.0 SQUARE METER OF SURFACE AREA',///
     8 3X,'PLEASE ENTER A RUN NUMBER TO CONTINUE ---> ',$)
      READ(*,*) CODE
C
C  OPEN FILES FOR PROGRAM OUTPUT
C
      WRITE(*,11)
   11 FORMAT(///,3X,'PLEASE SELECT AN OUTPUT FILE NAME ---> ',$)
      READ(*,12) OUTFIL
   12 FORMAT(A20)
C
      OPEN(UNIT=6,FILE=OUTFIL,STATUS='UNKNOWN')
C
   99 WRITE(*,13)
   13 FORMAT(///,3X,'PLEASE ENTER THE PARTITION COEF (Kd) ---> ',$)
      READ(*,14) KD
   14 FORMAT(F8.0)
C
      AREA = 10000
C
      WRITE(*,15)
   15 FORMAT(///,3X,'PLEASE ENTER WATER COLUMN DEPTH (cm) ---> ',$)
      READ(*,16) DEPWAT
   16 FORMAT(F8.0)
C
C  CALCULATE THE VOLUME OF WATER IN LITERS
C
```

```
      VOLWAT = DEPWAT * AREA / 1000.0
C
      WRITE(*,17)
   17 FORMAT(///,3X,'PLEASE ENTER THICKNESS OF SEDIMENT (cm) ---> ',$)
      READ(*,18) DEPSED
   18 FORMAT(F8.0)
C
C  CALCULATE THE VOLUME OF SEDIMENT IN LITERS
C
      VOLSED = DEPSED * AREA / 1000.0
C
      WRITE(*,20)
   20 FORMAT(///,3X,'PLEASE ENTER APPLICATION RATE (IN KG/HA) ---> ',$)
C
      READ(*,21) APRATE
   21 FORMAT(F8.0)
C
      WRITE(*,22)
   22 FORMAT(///,3X,'PLEASE ENTER PERCENT SPRAY DRIFT ---> ',$)
      READ(*,23) PCTDRF
   23 FORMAT(F8.0)
C
      DECDRF = (PCTDRF/100.0)
C
C  CALCULATE THE MASS OF PESTICIDE ENTERING THE 1.0 SQUARE METER AREA
C  IN MILLIGRAMS (1 kg/ha = 100 mg/m2)
C
      PSTTOT = APRATE * DECDRF * 100.0
C
      BDSED = 1.65
      BDWAT = 1.00
C
      MASSED = BDSED * VOLSED
      MASWAT = BDWAT * VOLWAT
C
      PSTWAT = (PSTTOT * VOLWAT) / (MASSED * KD + VOLWAT)
C
      PSTSED = PSTTOT - PSTWAT
C
      CONWAT = PSTWAT / VOLWAT
      CONSED = PSTSED / MASSED
C
C  WRITE OUTPUT TO THE SCREEN AND TO THE OUTPUT FILE
C
       WRITE(*,50)CODE
       WRITE(6,50)CODE
   50 FORMAT(////,3X,'RUN No.',I4,'          * INPUT VALUES *        ',/
     2 3X,'-------------------------------------------------------',/
     3 3X,' RATE    SPRAY DRIFT  APPLIED   SOIL Kd   WATER   SEDIMENT',/
     4 3X,'(kg/ha)    (percent)    (mg/m2)    (l/kg)    (cm)      (cm)  ',/
     5 3X,'-------------------------------------------------------')
C
      WRITE(6,52)APRATE,PCTDRF,PSTTOT,KD,DEPWAT,DEPSED
      WRITE(*,52)APRATE,PCTDRF,PSTTOT,KD,DEPWAT,DEPSED
```

```
C
   52 FORMAT(3X,F6.2,3X,F7.1,5X,F8.2,4X,F6.1,3X,F7.1,3X,F6.1)
C
      WRITE(*,60)
      WRITE(6,60)
C
   60 FORMAT(////,3X,'MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT ',/
     2 3X,'-------------------------------------------------------',/
     3 3X,'PEST-WAT  VOL-WAT  CONC-WAT   PEST-SED  MAS-SED  CONC-SED ',/
     4 3X,'  (mg)     (liter)    (mg/l)      (mg)      (kg)     (mg/kg)  ',/
     5 3X,'-------------------------------------------------------')
C
      WRITE(6,62)PSTWAT,VOLWAT,CONWAT,PSTSED,MASSED,CONSED
      WRITE(*,62)PSTWAT,VOLWAT,CONWAT,PSTSED,MASSED,CONSED
C
   62 FORMAT(3X,F8.2,1X,F8.1,F10.3,2X,F9.3,1X,F8.3,2X,F8.3)
C
      KDCHEK = CONSED / CONWAT
      TOTCHK = PSTWAT + PSTSED
C
      WRITE(*,*)
      WRITE(*,65) KDCHEK
      WRITE(*,66) TOTCHK
C
   65 FORMAT('   CONSED / CONWAT = ',F8.2)
   66 FORMAT('   PSTWAT + PSTSED = ',F8.2)
C
      WRITE(*,70)
   70 FORMAT(/////,3X,'DO YOU WANT TO DO ANOTHER RUN (Y OR N) ---> ',$)
      READ(*,80) AGAIN
   80 FORMAT(A1)
C
      IF(AGAIN.EQ.'Y'.OR.AGAIN.EQ.'y')THEN
        WRITE(*,90)
   90   FORMAT(///3X,'PLEASE ENTER A NEW RUN NUMBER ---> ',$)
        READ(*,*) CODE
C
        APRATE = 0
        APRATE = 0
        AREA = 0
        BDSED = 0
        BDWAT = 0
        CONSED = 0
        CONWAT = 0
        DEPSED = 0
        DEPWAT = 0
        KD = 0
        MASSED = 0
        MASWAT = 0
        PSTTOT = 0
        PSTSED = 0
        PSTWAT = 0
        DECDRF = 0
        PCTDRF = 0
```

```
        VOLSED = 0
        VOLWAT = 0
C
        GOTO 99
C
      ENDIF
C
      STOP
      END
```

&&&&&&&&&&&&&&&&&&&&&

Sample Input Summary and Output Files for KDCALC Program

RUN No. 15 * INPUT VALUES *

RATE (kg/ha)	SPRAY DRIFT (percent)	APPLIED (mg/m2)	SOIL Kd (l/kg)	WATER (cm)	SEDIMENT (cm)
.48	100.0	47.72	1.0	3.0	3.0

MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT

PEST-WAT (mg)	VOL-WAT (liter)	CONC-WAT (mg/l)	PEST-SED (mg)	MAS-SED (kg)	CONC-SED (mg/kg)
18.01	30.0	.600	29.712	49.500	.600

RUN No. 16 * INPUT VALUES *

RATE (kg/ha)	SPRAY DRIFT (percent)	APPLIED (mg/m2)	SOIL Kd (l/kg)	WATER (cm)	SEDIMENT (cm)
.06	100.0	6.44	1.0	3.0	3.0

MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT

PEST-WAT (mg)	VOL-WAT (liter)	CONC-WAT (mg/l)	PEST-SED (mg)	MAS-SED (kg)	CONC-SED (mg/kg)
2.43	30.0	.081	4.010	49.500	.081

RUN No. 17 * INPUT VALUES *

RATE (kg/ha)	SPRAY DRIFT (percent)	APPLIED (mg/m2)	SOIL Kd (l/kg)	WATER (cm)	SEDIMENT (cm)
.02	100.0	2.13	1.0	3.0	10.0

MASS & CONC OF PESTICIDE IN WATER AND SEDIMENT

PEST-WAT	VOL-WAT	CONC-WAT	PEST-SED	MAS-SED	CONC-S

Appendix D. Ecological Toxicity Summary

Toxicity to Terrestrial Animals

Avian (Acute and Subacute Toxicity)

Table B-1. Avian Acute Oral Toxicity

Species	% a.i.	LD_{50} (mg/kg)	Toxicity Category	MRID # Author/Year	Study Classification
Bobwhite Quail (*Colinus virginianus*)	97.4	152.3	Moderately toxic	42055308/Toll /1990	Core
House Sparrow (*Passer domesticus*)	2.5G	41.0	Highly toxic	42055309/ Stafford/1990	Supplemental
Japanese Quail (*Coturnix japonica*)	95.3	31	Highly toxic	43310401 Grau/1988	Supplemental

Since the LD_{50} is 31 mg/kg, imidacloprid technical appears to be highly toxic to Japanese quail. A study on the granular product (2.5G) also suggests that exposure of the compound to small birds (house sparrow) can result in high toxicity (41 mg/kg).

Table B-2. Avian Subacute Dietary Toxicity

Species	% a.i.	5-day LC_{50} (ppm)	Toxicity Category	MRID # Author/Year	Study Classification
Bobwhite Quail (*Colinus virginianus*)	94.8	1,536	Slightly toxic	42055310/Toll/ 1990	Core
Mallard duck (*Anas platyrhynchos*)	94.8	> 4,797	Practically non-toxic	42055311/Toll /1990	Core

The LC_{50} values of 1,536 - 4,797 ppm suggest that imidacloprid is practically non-toxic to mallard ducks and slightly toxic to Bobwhite quail after dietary exposure.

Avian (Chronic Toxicity)

Table B-3. Avian Reproduction Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Toxicity Endpoints Affected	MRID # Author/Year	Study Classification
Bobwhite Quail (*Colinus virginianus*)	94.8	36/ >61	Egg shell thinning and decrease in adult weights	42055312/Toll /1991	Core

Mallard duck (*Anas platyrhynchos*)	94.8	125/ >125	Egg shell thinning and decrease in adult weights	42055313/Toll /1991	Supplemental
Mallard duck (*Anas platyrhynchos*)	94.8	47/61	Egg shell thinning	43466501	Supplemental

The chronic studies that were submitted show that imidacloprid exposure of 61 ppm to Bobwhite quail may result in egg shell thinning and decreased adult weight.

Mammals (Acute and Chronic Toxicity)

Table B-4 Mammalian Acute Toxicity

Species	% a.i.	LD50 (mg/kg)	Toxicity Category	MRID # Author/Year	Study Classification
Laboratory Rat (*Rattus norvegicus*)	2.5G	> 4,820	Practically non-toxic	42055324	Core
Laboratory Rat (*Rattus norvegicus*)	Tech	424	Moderately toxic	42055331	Core
Laboratory Rat (*Rattus norvegicus*)	97.6	LOAEL =151	-	41370301 43285801	Core
Laboratory mouse	10	1,838	Slightly toxic	42679601	Core

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, the intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects division (HED) substitute for wild mammal testing. Since imidacloprid is a neurotoxic chemical there is evidence of functional neurotoxicity in treated rats. A single oral dose caused a dose-related decrease in motor or locomotor activity with a LOAEL = 151 mg/kg. The LD50 = 424 mg/kg suggesting moderate toxicity.

Table B-5. Mammalian Reproductive Toxicity

Species	% a.i.	Toxicity Value NOAEL (mg/kg)	MRID #	Study Classification
Laboratory rat	tech	250 ppm	42256340	Core

The results of the mammalian reproduction studies suggest that imidacloprid may cause reproductive effects at an exposure level of 250 ppm and above.

Toxicity to Beneficial Insects

Table B-6. Nontarget Insect Studies

Species	% a.i.	Endpoint	Toxicity Category	MRID # Author/Year	Study Category
Honey bee (*Apis mellifera*)	99.8	LD_{50} (µg/bee) = 0.078 (contact)	Very highly toxic	42273003/Cole /1990	Core
Honey bee (*Apis mellifera*)	99.8	LD_{50} (µg/bee) = 0.0039 (oral)	Very highly toxic	42273003/Cole /1990	Core
Honey bee (*Apis mellifera*)	240 FS TEP 0.5 lb a.i./A	RT_{25} = 8hrs	N/A	42632901/ Hancock et al./1992	Core

Acute toxicity testing on honeybees suggest that imidacloprid is very highly toxic (0.0039 - 0.078 ug/bee) to non-target insects.

Toxicity to Freshwater Aquatic Organisms

Freshwater Fish (Acute)

Table B-7. Acute Toxicity for Freshwater Fish

Species	% a.i.	LC_{50} (ppm)	Toxicity Category	MRID # / Author/ Date	Study Classification
Rainbow trout (*Oncorhynchus mykiss*)	97.4	> 83	Practically non-toxic	42055315/ Bowman/1990	Core
Bluegill sunfish (*Lepomis macrochirus*)	97.4	> 105	Practically non-toxic	42055314/ Bowman/1990	Core

Acute toxicity testing on the preferred species, rainbow trout and bluegill sunfish, resulted in 96-hour LC_{50} values of 83 - 105 ppm. This suggest that imidacloprid is practically non-toxic to freshwater fishes on an acute basis.

Freshwater Fish (Chronic)

Table B-8. Freshwater Fish Chronic Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Endpoints Affected	MRID #/ Author/Date	Study Classification
Rainbow trout (*Oncorhynchus mykiss*)	95	1.2 / 2.5	Weight and length	42055320/ Bowman/1990	Supplemental

The results from a rainbow trout early life stage study suggest that imidacloprid exposure can result in growth effects (1.2 ppm) to freshwater fish.

Freshwater Invertebrates (Acute)

Table B-9. Freshwater Invertebrate Acute Toxicity

Species	% a.i.	48 Hour EC_{50} (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Daphnid (*Daphnia magna*)	95.4	85.2	Slight toxicity	42055317/ Young/1990	Core
Amphipod (*Hyalella azteca*)	tech	0.115	Very highly toxic	42256303/ England & Bucksath/1991	Core
Midge (*Chironomus tentans*)	tech.	0.069	Very highly toxic	42256304/ Gagliano/1991	Core
Midge (*Chironomus tentans*)	Desnitro (guanidine) degradate	--	--	43946602/ Bowers/1996	*In Review*
Amphipod (*Hyalella azteca*)	Desnitro (guanidine) degradate	--	--	43946601/ Roney and Bowers/1996	*In Review*
Midge (*Chironomus tentans*)	6-chloronicotinic acid degradate	--	--	44558901/ Bowers and Lam/1998	*In Review*
Midge (*Chironomus tentans*)	Urea degradate	--	--	43946604/ Dobbs and Frank/1996	*In Review*
Amphipod (*Hyalella azteca*)	Urea degradate	--	--	43946603/ Dobbs and Frank/ 1996	*In Review*

Imidacloprid is categorized as very highly toxic (0.069 - 0.115 ppm) to freshwater invertebrates on an acute basis.

Table B-10. Freshwater Invertebrate Chronic Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Endpoints Affected	MRID #/ Author/Date	Study Classification
Daphnid (*Daphnia magna*)	95.9	1.8 / 3.6	Growth and movement	42055321/ Young/1990	Supplemental

Imidacloprid exposure to freshwater invertebrates can potentially result in growth effects at 3.6 ppm.

Toxicity to Estuarine and Marine Organisms

Estuarine and Marine Fish (Acute)

Table B-11. Estuarine/Marine Acute Toxicity

Species	% a.i.	96-hour LC50 (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Sheepshead Minnow (*Cyprinodon variegatus*)	92.2	163	Practically non-toxic	42055318/ Ward/1990	Core

Imidacloprid exposure to estuarine/marine fish is expected to be practically non-toxic on an acute basis (135 ppm).

Estuarine and Marine Fish (Chronic)

No estuarine/marine chronic studies have been submitted at this time.

Estuarine and Marine Invertebrates (Acute)

Table B-12. Estuarine/Marine Invertebrate Acute Toxicity

Species	% a.i.	48 Hour EC_{50} (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Mysid Shrimp (*Mysidopsis bahia*)	96.2	0.037	Very highly toxic	42055319/ Ward/1990	Core
Eastern Oyster (*Crassostrea virginica*)	95.8	> 145	practically non-toxic	42256305/ Wheat/1991	Supplemental

Imidacloprid is very highly toxic to estuarine/marine invertebrates (mysid shrimp) on an acute basis (0.037 ppm). However, it appears that bivalves may be more tolerant and may avoid acute exposure (> 145 ppm).

Estuarine and Marine Invertebrates (Chronic)

Table B-13. Estuarine/Marine Invertebrate Life-Cycle Toxicity

Species	% a.i.	NOAEC/ LOAEC (ppm)	Endpoints Affected	MRID #/ Author/Date	Study Classification
Mysid Shrimp (*Mysidopsis bahia*)	96.2	>0.0006 / 0.0013	Growth and Survival	42055322/ Ward/1990	Core

The results of this study suggest that chronic exposure of imidacloprid to estuarine/marine invertebrates can result in growth and survival effects (0.0013 ppm).

Aquatic Plants

Table B-14. Aquatic Plants

Species	% a.i.	EC_{50} (ppm)	Toxicity Category	MRID #/ Author/Date	Study Classification
Green Algae *Scenedesmus subspicatus*	92.8	> 10	N/A	42256374/ Heimbach/1989	Supplemental
Duckweed *Lemna gibba*	98.8	--	--	48648601/ Banman et al./ 2011	*In review*

EFED requires Tier I aquatic growth studies on 5 aquatic plants, including 1 vascular and 4 non-vascular taxa.

Terrestrial Plants

Table B-15. Terrestrial Plants

Study type	Formulation	EC_{25} (lb/A)	MRID #/ Author/Date	Study Classification
Vegetative Vigor	SC 240D G	--	48648602/Bach/ 2011	*In review*
Seedling Emergence	SC 240D G	--	48648603/Bach/ 2011	*In review*

EFED requires Tier I vegetative vigor and seedling emergence studies on 10 terrestrial plant species, including 4 monocot and 6 dicot species.

Appendix E. List of imidacloprid studies used in the risk assessment that were submitted to the European Food Safety Authority but not to the Agency.

Dorgerloh, M. and Sommer, H. 2001. Influence of Imidacloprid SL 200 on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer CropScience AG, unpublished report No.: DOM 21064, November 14, 2001, WAT2003-660.

Dorgerloh, M. and Sommer, H. 2001. Influence of Imidacloprid (tech.) on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: DOM 21035; Date: 2001-10-04, WAT2003-648.

Dorgerloh, M. and Sommer, H. 2001. Influence of Imidacloprid-desnitro on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Bayer CropScience AG, unpublished report No.: DOM 21039, Date: 2001-10-26 WAT2003-649.

Dorgerloh, M. and Sommer, H. 2002. Acute toxicity of imidacloprid-nitroso to Larvae of *Chironomus riparius*. Bayer CropScience AG, unpublished report no.: DOM 22032, April 18, 2002, WAT2003-654.

Dorgerloh, M. and Sommer, H. 2002. Acute toxicity of imidacloprid-5-hydroxy to Larvae of *Chironomus riparius*; Bayer CropScience AG, unpublished report no.: DOM 22033, April 18, 2002 WAT2003-655.

Grau, R. 1996. NTN 33893 techn.: 5-Day Dietary LC_{50} to Japanese quail. Bayer CropScience AG, unpublished report No. GMU/VW-177. Date: 1996-03-14. Amended: 2002-01-28, AVS 98-00136.

Hendel, B. 2001. Influence of NTN 33893-AMCP on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: HDB/Ch 49; Date: 2001-5-10, WAT2003-651.

Hendel, B. 2001. Influence of NTN 33893-urea on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: HDB/Ch 48; Date: 2001-06-08, WAT2003-652.

Hendel, B. 2001. Influence of imidacloprid (tech.) of *Gammarus pulex* in a water-sediment system. Bayer CropScience AG, unpublished report No.: HDB/SP 01-00, April 5, 2001, PFL2003-191.

Hendel, B. and Sommer, H. 2001. Influence of Imidacloprid-desnitro-olefine on development and emergence of larvae of *Chironomus riparius* in a water-sediment system; Bayer CropScience AG, unpublished report No.: HDB/Ch 51; Date: 2001-11-26; WAT2003-650.